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Biological therapy

National clinical audit of biological therapies

UK inflammatory bowel disease (IBD) audit

Adult report
September 2015

Prepared by the Clinical Effectiveness and Evaluation Unit at the Royal
College of Physicians on behalf of the IBD programme steering group



The Royal College of Physicians

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Healthcare Quality Improvement Partnership

The national clinical audit of biological therapies is commissioned by the Healthcare Quality Improvement Partnership (HQIP) as part of the National Clinical Audit Programme (NCA). HQIP is led by a consortium of the Academy of Medical Royal Colleges, the Royal College of Nursing and National Voices. Its aim is to promote quality improvement, and in particular to increase the impact that clinical audit has on healthcare quality in England and Wales. HQIP holds the contract to manage and develop the NCA Programme, comprising more than 30 clinical audits that cover care provided to people with a wide range of medical, surgical and mental health conditions. The programme is funded by NHS England, the Welsh Government and, with some individual audits, also funded by the Health Department of the Scottish Government, DHSSPS Northern Ireland and the Channel Islands.

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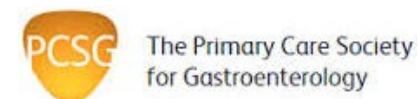
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Document purpose	To disseminate the results of the national inflammatory bowel disease (IBD) biological therapy audit
Title	National clinical audit of biological therapies. UK inflammatory bowel disease (IBD) audit. Adult report. September 2015.
Author	On behalf of the IBD programme steering group
Publication date	24 September 2015
Audience	Healthcare professionals, NHS managers, service commissioners and policymakers
Description	This is the fourth biological therapy report published from the UK IBD audit. This report is addressed to anyone who is interested in IBD. It publishes national- and hospital-level findings on the efficacy, safety and appropriate use of biological therapies for patients newly started on biologics since its inception on 12 September 2011 until 28 February 2015.
Supersedes	National clinical audit of biological therapies. UK inflammatory bowel disease (IBD) audit. Adult report. September 2014.
Related publications	<p>IBD Standards Group, 2013. <i>Standards for the healthcare of people who have inflammatory bowel disease, IBD standards, 2013 update</i>. www.ibdstandards.org.uk</p> <p>Mowat C, Cole A, Windsor A <i>et al</i>, on behalf of the IBD Section of the British Society of Gastroenterology. Guidelines for the management of inflammatory bowel disease in adults. <i>Gut</i> 2011;60:571–607.</p> <p>National Institute for Health and Care Excellence, 2008. Technology appraisal 163: <i>Infliximab for acute exacerbations of ulcerative colitis</i>. www.nice.org.uk/guidance/TA163</p> <p>National Institute for Health and Care Excellence, 2011. Technology appraisal 187: <i>Infliximab (review) and adalimumab for the treatment of Crohn's disease</i>. www.nice.org.uk/guidance/TA187</p> <p>National Institute for Health and Care Excellence, 2015. Technology appraisal 329: <i>Infliximab, adalimumab and golimumab for treating moderately to severely active ulcerative colitis after the failure of conventional therapy (including a review of TA140 and TA262)</i>. www.nice.org.uk/guidance/TA329</p> <p>National Institute for Health and Care Excellence, 2015. Quality standard 81: <i>Inflammatory bowel disease</i>. www.nice.org.uk/guidance/QS81</p> <p>Royal College of Physicians, 2014. <i>Experience of inpatients with ulcerative colitis throughout the UK</i>.</p> <p>Royal College of Physicians, 2014. <i>National audit of inflammatory bowel disease (IBD) service provision. Adult report</i>.</p> <p>Royal College of Physicians, 2014. <i>National clinical audit of inpatient care for adults with ulcerative colitis</i>.</p>
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Commissioned by:



In partnership with:



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Report preparation

The report was prepared by the biological therapy audit subgroup on behalf of the IBD programme steering group. (A full list of steering group members can be found in **Appendix 2.**)

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The IBD programme steering group would like to thank all hospitals that continue to contribute to this national audit. We would also like to thank all who have participated in piloting and development of the UK IBD audit since it began in 2005. Thanks also to participating NHS hospitals that have provided invaluable suggestions on ways to improve the audit. The web-based data collection tool was developed by Westcliff Solutions Ltd: www.westcliffsolutions.co.uk

Executive summary

Background

Biological therapies are the newest group of drugs to be used in inflammatory bowel disease (IBD). Most of these drugs work by targeting a protein in the body called tumour necrosis factor alpha (TNF α). Overproduction of this protein is thought to be partly responsible for the chronic inflammation in patients with IBD.

The purpose of this audit is to measure the efficacy, safety and appropriate use of the biological therapies infliximab and adalimumab, also known as anti-TNF α drugs, in patients with IBD in the UK. The audit also aims to capture patients' views on their quality of life at intervals during their treatment.

This is the fourth report of the biological therapy element of the UK IBD audit; all analyses within this report include only those patients who were newly started on biological therapies between 12 September 2011 (the start of data collection) and 28 February 2015. The data contained within this report have **only** been taken from completed submissions within the biological therapy audit web tool (www.ibdbiologicsaudit.org).

The biological therapies audit provides IBD teams with the means to meet Standard A6 of the **IBD standards**;¹ specifically, regular review of patient outcomes and auditing of biological therapy. Participation in the audit provides the opportunity to review compliance with National Institute for Health and Care Excellence (NICE) recommendations **technology appraisal 187**² and **technology appraisal 329**³ and also fulfils NICE quality statement 4: monitoring drug treatment in **quality standard 81**.⁴

Key messages

Participation in the biological therapies audit has improved substantially over time. Of 159 adult trusts / health boards eligible to participate in this audit, 152 (96%) are participating in either the audit or the Personalised Anti-TNF Therapy in Crohn's disease study (PANTs).⁵ A total of 4718 adult patients have now been included in this national analysis. This is a clear demonstration of the effectiveness of collaboration between national audit and research, which results in a reduced burden of data entry for clinicians and greater engagement.

At some sites, data from only a minority of cases are being entered. The organisational audit in 2013 collected data on the number of patients newly started on biological therapies. Although 40% of sites estimated this figure, when current data are compared with this, it appears possible that only 22% of eligible new starters have been audited.

The data presented in this report demonstrate that biological therapies for IBD are effective and relatively safe treatments. Patterns of use are changing, with earlier use in patients with less severe disease. It is likely that this reflects more appropriate prescribing as physicians become more familiar with these drugs. It is also clear that only a minority of patients have their treatment stopped when effective, as recommended in the NICE guidance. Further audit will clarify this issue, identifying those patients in whom treatment can be stopped. These data are vital for local quality improvement.

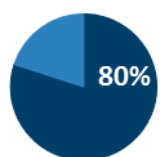
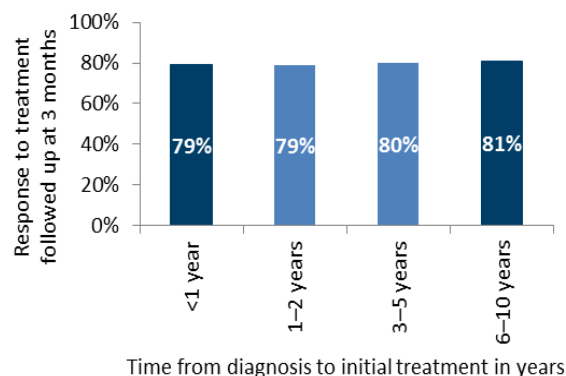
Key findings

Clinical findings

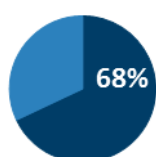
41%

of audited adult patients were being treated with biological therapies within 2 years of being diagnosed with Crohn's disease (CD). (Section 5, p 35)

Response to treatment is not related to duration of disease: the response rate was 79% in patients treated within 1 year of diagnosis and 81% in those treated 6–10 years from diagnosis. (Section 2, p 21)



80% Response to treatment



68% Remission achieved

Treatment of CD with a biological therapy is effective: 80% of adult patients audited experienced a response, with remission in 68%. (Section 2, p 21)

Quality of life also improved after treatment, with a 61% reduction in median Crohn's and ulcerative colitis questionnaire (CUCQ)-12 scores. (Section 2, p 28)

Over the last three rounds of audit, pre-treatment Harvey–Bradshaw index (HBI) has fallen from 9 to 7. (Section 2, p 22)



58% Immunosuppression



34%

Use of concomitant immunosuppression therapy has also fallen from 58% to 34%, which suggests earlier use of biological therapies in patients with milder disease. (Section 2, p 22)



8%

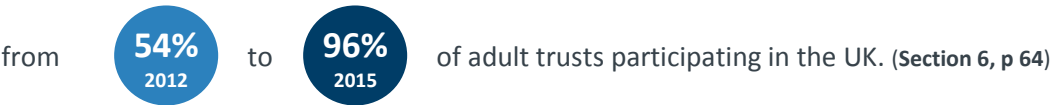
of patients reported an adverse event when assessed at 3-month follow-up. Infection was seen in 2% of patients and mortality in 0.1%; no malignancies were reported. (Section 2, p 25)

Treatment was stopped in **9%** of patients with CD who were followed up at 12 months.

The audit data suggest that the treatment was discontinued because it was effective in 34% of these patients, while another 23% stopped treatment after experiencing side effects / an adverse event. (Section 5, p 43)

Participation findings

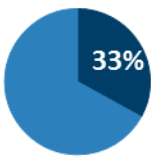
The number of sites engaging with the biological therapy audit since its inception has been gradually increasing:



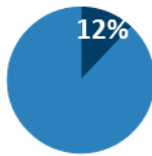
Although participation in the audit has improved over time, only about 1 in 5 eligible patients were audited in 2013. (Section 2, p 24)



Submission of follow-up data has improved but remains incomplete. (Section 2, p 19)

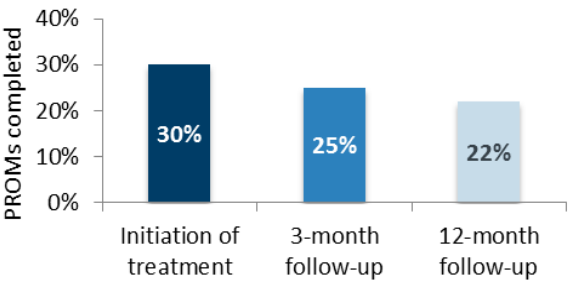


Only 33% of adult patients audited had complete follow-up data at 3 months.



The proportion is even lower for 12-month follow-up, with only 12% of patients recorded as having been followed up at this timepoint.

More patient-reported outcome measures (PROMs) were completed at the start of treatment (30%) than for the previous report (14%), although fewer PROMs were completed at the 3- and 12-month review points (25% and 22%, respectively).⁶ (Section 2, p 28)



Recommendations

- 1 Sites that prescribe and administer biological therapies to their patients with inflammatory bowel disease (IBD) should continue to participate in the national biological therapy audit. They should aim to submit complete data on all new starters. This includes data at baseline and at least 3- and 12-month follow-up. Sites that enter data to the Personalised Anti-TNF Therapy study (PANTs) are counted as participating; these sites are reminded that data on patients not applicable for inclusion in the research study should be entered into the biological therapy audit web tool so that all new starters on biological therapies are captured.
- 2 Disease activity should be routinely assessed and monitored, especially at baseline and again at 3- and 12-month follow-up.
- 3 Sites should continue to encourage patients to complete patient-reported outcome measures (PROMs) at baseline, as they provide an indication of patient outcomes and the quality of care delivered to patients. It is important to ensure that PROMs are completed at follow-up.
- 4 The audit has been extended to include patients started on biosimilar versions of infliximab and other biological treatments. Patients newly started on these treatments should now be audited.
- 5 Sites should use the 'Export data' function of the web tool to check the completeness of the data entered. Exported data can also be used for any local analyses, which can support quality improvement activities.
- 6 Sites should continue to monitor safety and efficacy over the long term and should stop biological therapies in patients who have failed to respond to treatment.
- 7 The findings and recommendations of this report should be shared at relevant multidisciplinary team, clinical governance and audit meetings, and a local action plan for implementing change should be devised.

Implementing change: action plan

This action plan has been produced to enable you to take forward the recommendations of this national audit. It can be adapted through the addition of further actions that you feel are appropriate for your own service. You can download a copy of this action plan from www.rcplondon.ac.uk/ibd.

National recommendation	Action required	Staff responsible	Progress at your site (Include date of review, name of individual responsible for action)
1 Sites that prescribe and administer biological therapies to their patients with inflammatory bowel disease (IBD) should continue to participate in the national biological therapy audit. They should aim to submit complete data on all new starters. This includes data at baseline and at least 3- and 12-month follow-up. Sites that enter data to the Personalised Anti-TNF Therapy in Crohn's disease study (PANTs) are counted as participating; these sites are reminded that data on patients not applicable for inclusion in the research study should be entered into the biological therapy audit web tool so that all new starters on biological therapies are captured.	Eligible sites should ensure that all newly started patients are entered into the biological therapies audit. Have a system in place to ensure that data are collected at 3- and 12-month follow-up.	Consultant gastroenterologists IBD nurses Infusion clinic staff	
2 Disease activity should be routinely assessed and monitored, especially at baseline and again at 3- and 12-month follow-up.	Ensure that the relevant disease activity index is available in clinical areas. Ensure that IBD clinical teams are made aware of its availability and importance. Disease activity scoring forms for patients can be downloaded directly from the biological therapy audit web tool (www.ibdbiologicsaudit.org).	Consultant gastroenterologists IBD nurses Infusion clinic staff	

National recommendation	Action required	Staff responsible	Progress at your site (Include date of review, name of individual responsible for action)
3 Sites should continue to encourage patients to complete patient-reported outcome measures (PROMs) at baseline, as they provide an indication of patient outcomes and the quality of care delivered to patients. It is important to ensure that PROMs are completed at follow-up.	Ensure that the PROM forms are available in clinical areas. Ensure that IBD clinical teams are made aware of their availability and importance. PROM forms for patients can be downloaded directly from the biological therapy audit web tool (www.ibdbiologicsaudit.org).	Consultant gastroenterologists IBD nurses Infusion clinic staff	
4 The audit has been extended to include patients started on biosimilar versions of infliximab and other biological treatments. Patients newly started on these treatments should now be audited.	Ensure that data on all patients newly started on biosimilar versions of drugs are entered into the biological therapies audit. Have a system in place to ensure that data are collected at 3- and 12-month follow-up.	Consultant gastroenterologists IBD nurses Infusion clinic staff	
5 Sites should use the 'Export data' function of the web tool to check the completeness of the data entered. Exported data can also be used for any local analyses, which can support quality improvement activities.	Ensure that staff are aware that the export function can be used at any time. Site-level data can be analysed at any time, independent of the annual report. Data can be exported directly from the biological therapy audit web tool by clicking the 'Export data' function (www.ibdbiologicsaudit.org).	NHS managers Consultant gastroenterologists	
6 Sites should continue to monitor safety and efficacy over the long term and should stop biological therapies in patients who have failed to respond to treatment.	In keeping with guidance from the National Institute for Health and Care Excellence (NICE), processes should be put in place to ensure that patients are assessed at 12 months.	Consultant gastroenterologists Infusion clinic staff	

National recommendation	Action required	Staff responsible	Progress at your site (Include date of review, name of individual responsible for action)
7 The findings and recommendations of this report should be shared at relevant multidisciplinary team, clinical governance and audit meetings, and a local action plan for implementing change should be devised.	Identify an appropriate time to discuss the results of the audit and decide key priority areas for improvement. Present the findings and recommendations at an appropriate meeting and ensure that action plans for implementing change are devised.	NHS managers Consultant gastroenterologists IBD nurses Members of the IBD team	
8 ENTER THE LOCAL ACTIONS YOU HAVE IDENTIFIED HERE			
9 ENTER THE LOCAL ACTIONS YOU HAVE IDENTIFIED HERE			

1: Introduction and methods

Introduction

Biological therapies are the newest group of drugs to be used in inflammatory bowel disease (IBD). Most of these drugs work by targeting a protein in the body called tumour necrosis factor alpha (TNF α). Overproduction of this protein is thought to be partly responsible for the chronic inflammation in patients with IBD. Biological therapies have revolutionised the treatment of IBD, with usage increasing rapidly in the UK over the past few years. Available data suggest that they are effective treatments, with a relatively low frequency of adverse events. They remain a significant cost burden for hospitals in the UK – approximately £10,000 per patient per year – and thus audit of their effectiveness, safety and appropriateness remains a clinical priority. Further information about biological therapies and their licensing can be found in **section 4, p 30**.

Aims of the biological therapies audit

To assess nationally:

- 1 the appropriate use/prescribing of biological therapies in the treatment of IBD
- 2 the efficacy of biological therapies in the treatment of IBD
- 3 the safety of biological therapies in the treatment of IBD
- 4 the views of patients with IBD on their quality of life at defined intervals throughout their use of biological therapies.

Methods

This is a prospective audit, with data collection taking place in 'real time' during the clinical appointment with the patient. Participating sites are asked to identify and enter data on patients newly started on biological therapies. Data entry takes place in the form of 'submissions' to a web-based data collection tool (www.ibdbiologicsaudit.org). A submission refers to data entered in any of the following categories: patient demographics, IBD disease details, initial anti-TNF α treatment, follow-up anti-TNF α treatment and IBD-related surgery. Further detail about each of the categories can be found on **p 31** of this report.

Definition of a 'site'

Lead clinicians are asked to collect and submit data on the basis of a unified IBD service that would be registered as a named 'site'. This is typically a single hospital within a trust / health board, but where more than one hospital under a trust / health board offers independent IBD services, data are entered for separate 'sites'. Some organisations that run a coordinated IBD service across several hospitals with the same staff participate in the audit as one trust / health board-wide site.

Eligibility and participation

Sites are eligible to participate in the biological therapies audit if they prescribe and administer biological therapy to their patients with IBD. Of the 159 adult trusts / health boards eligible to participate in the IBD audit in the UK, 152 are participating in the biological therapies element and/or in the Personalised Anti-TNF Therapy in Crohn's disease (CD) study (PANTs); see below for further information). These 152 trusts / health boards provided the 194 sites that submitted data. Further information on participation and a list of participating and non-participating sites can be found in **section 6, p 64** of this report.

PANTs

This is a 3-year, prospective, uncontrolled, cohort study investigating primary non-response, loss of response and adverse drug reactions to infliximab and adalimumab in patients with severe, active, luminal CD. The collected clinical data are aligned with data collected by the biological therapy audit. Relevant anonymised data from PANTs have been included and analysed in this report. Sites participating in PANTs are reminded that patients not eligible for inclusion in this research study should

still be entered on to the biological therapy audit web tool so that all new starters are captured. Sites submitting data to PANTs are indicated by an asterisk in the list of participating and non-participating sites in **section 6, p 64** of this report.

Inclusion and exclusion criteria

Only patients with diagnosed IBD – that is, CD, ulcerative colitis (UC) and IBD type unclassified (IBDU) – who have been started on biological therapy for the treatment of their IBD are included. Patients of all ages are included in the audit. Sites that do not provide any biological treatment to their patients with IBD are excluded from participation. The process of including and excluding data in national analyses is detailed in the consort diagram on **p 18** of this report.

Denominators

Denominators throughout the report vary depending on the number of submissions to which the analysed data relate. A submission refers to data entered in any of the following categories: patient demographics, IBD disease details, initial treatment, follow-up treatment and IBD-related surgery. For example, a single patient can have multiple initial or follow-up treatments and may have been treated with one or both drug types. The denominators can vary considerably, so readers should review all table notes and explanatory text provided within the report.

Data-collection tool

Security and confidentiality are maintained during data collection by using unique usernames and passwords; only the lead clinician at each site can authorise local access. Data can be saved during and at the end of an input session, and online help – including definitions and clarifications of data items, internal logical data checks and instant feedback mechanisms – ensure that high-quality data are collected. For an explanation of the different submission types in the biological therapies audit, please see **p 31** of this report.

Site-level data

The small numbers of patients with UC and IBDU mean that site-level data are restricted to patients with CD. The IBD programme steering group, having taken statistical advice, has identified a sample size of fewer than six patients as potentially compromising patient anonymity in the age and gender fields in Table 2. Results in site reports that meet this criterion have therefore been replaced with ‘n<6’. In the case of the national report, no data will appear in the ‘Your site’ columns, but these have been left *in situ* to show the format of the individualised site reports.

Evidence

Guidance referred to within this document is taken from the following sources:

- IBD Standards Group, 2013. *Standards for the healthcare of people who have inflammatory bowel disease, IBD standards, 2013 update*. www.ibdstandards.org.uk [Accessed 16 July 2015].
- Mowat C, Cole A, Windsor A *et al*, on behalf of the IBD Section of the British Society of Gastroenterology. Guidelines for the management of inflammatory bowel disease in adults. *Gut* 2011;60:571–607.
- National Institute for Health and Care Excellence, 2008. Technology appraisal 163: *Infliximab for acute exacerbations of ulcerative colitis*. www.nice.org.uk/guidance/TA163. [Accessed 16 July 2015].
- National Institute for Health and Care Excellence, 2011. Technology appraisal 187: *Infliximab (review) and adalimumab for the treatment of Crohn’s disease*. www.nice.org.uk/guidance/TA187 [Accessed 16 July 2015].
- National Institute for Health and Care Excellence, 2015. Technology appraisal 329: *Infliximab, adalimumab and golimumab for treating moderately to severely active ulcerative colitis after the failure of conventional therapy (including a review of TA140 and TA262)*. www.nice.org.uk/guidance/TA329 [Accessed 16 July 2015].

- National Institute for Health and Care Excellence, 2015. Quality standard 81: Inflammatory bowel disease. www.nice.org.uk/guidance/QS81 [Accessed 16 July 2015].
- Royal College of Physicians, 2014. *Experience of inpatients with ulcerative colitis throughout the UK*.
- Royal College of Physicians, 2014. *National audit of inflammatory bowel disease (IBD) service provision. Adult report*.
- Royal College of Physicians, 2014. *National clinical audit of inpatient care for adults with ulcerative colitis*.

Availability of audit results in the public domain

Full and executive summary copies of this report are available in the public domain via the Royal College of Physicians (RCP) website (www.rcplondon.ac.uk/biologics). The national report of results will be made available to NHS England; the Department of Health, Social Services and Public Safety in Northern Ireland; Healthcare Improvement Scotland; and the Department for Health and Social Services in Wales. A number of key indicators for each of the 194 participating sites are published in the public domain in **section 6, pp 64–85** of this report; these findings are also available via www.data.gov.uk, in line with the government's transparency agenda.

Presentation of results

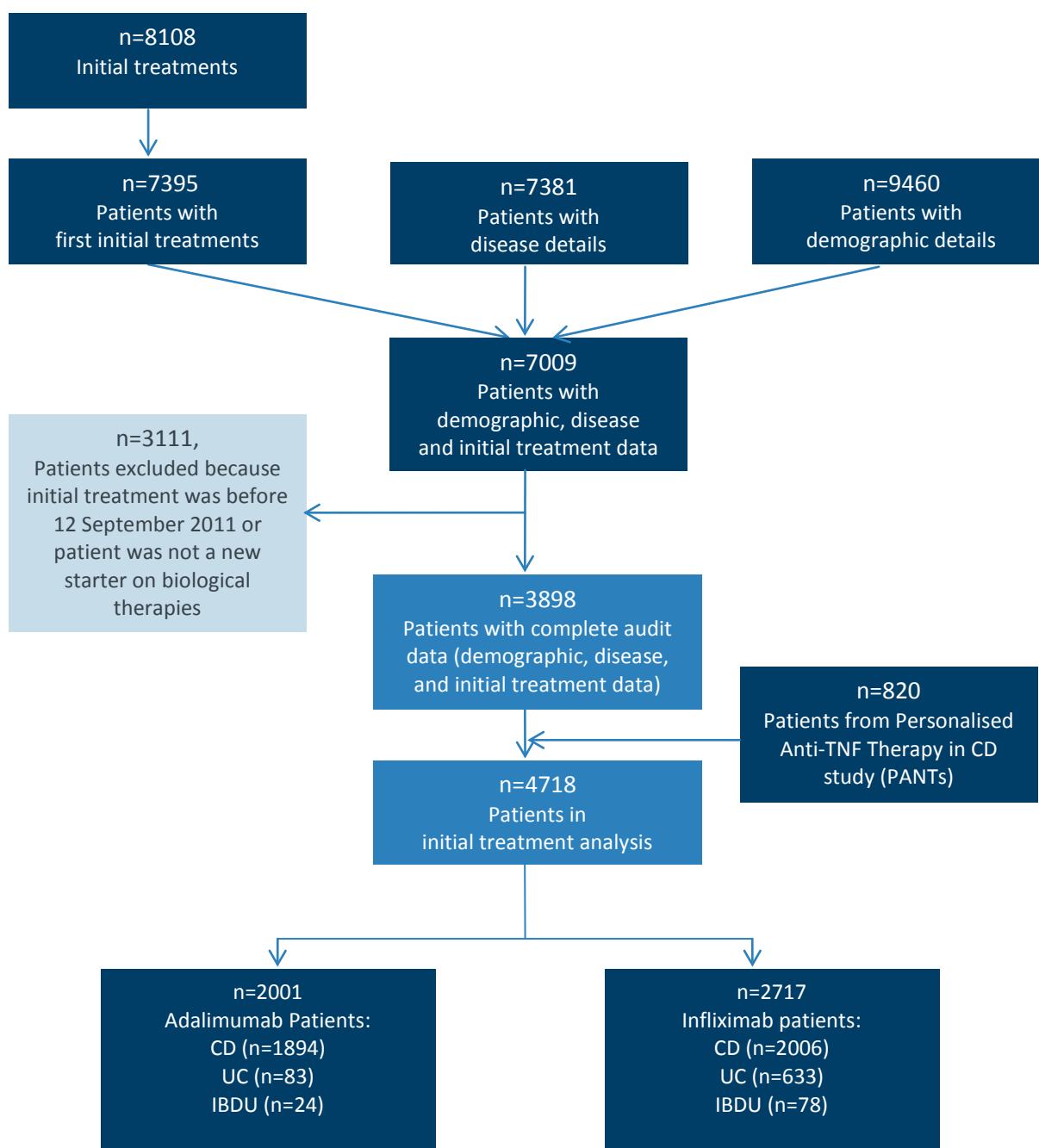
National results are presented as percentages for categorical data and as medians and interquartile ranges (IQRs) for numerical data. This report summarises data on adults provided by sites that registered to participate in the audit and indicated that they provide their IBD service to mainly adult patients. A separate report for paediatric IBD services can be viewed on the RCP website (www.rcplondon.ac.uk/biologics). When measures are comparable, both adult and paediatric data are provided for review.

2: Summary of key results

Consort diagram – initial treatment

On 28 February 2015, 9460 individual adult patient demographic submissions had been entered on the web tool. Readers are reminded that individual results are often a subset of this number and that the context and actual number of cases should be considered when interpreting findings. Fig 1 is therefore integral to understanding the patient numbers and the reasons that patients were excluded from analysis when considering the results in this report.

Fig 1 Consort diagram for initial treatment. CD = Crohn's disease; IBDU = inflammatory bowel disease type unclassified; UC = ulcerative colitis.



All analyses within this report include all patients who were newly started on biological therapies since 12 September 2011 (the start of the audit). A consort diagram detailing patient numbers and reasons for exclusion from follow-up treatment data can be found in **Appendix 3, p 96**.

Key data tables

Understanding these results

The tables in this section use key data items to address the objectives of the biological therapies audit and provide an overall view of the main characteristics of the included patients. It is important to note that this report is patient focused rather than treatment based; therefore, although some of the tables may appear similar to those in the reports produced in 2013 and 2014, these analyses have been conducted differently, so it is not advisable to compare directly with those in the previous reports.

Table 1 Patient summary

This table provides a summary of the patients and treatments included in the national analysis. The consort diagram in Fig 1 (p 18) shows that only those patients with at least one initial treatment were included in the analyses. Thereafter, the numbers reduce based on whether patients were recorded as having been followed up at 3 and 12 months after initial treatment. For the follow-up timepoint, a 1-month window either side was used in order to best capture patients – eg for 3-month follow-up, data entered 60–120 days after initial treatment were included.

Patient group	Initial treatment (n)	3-month follow-up (n)	12-month follow-up (n)
CD patients	3900	1343	520
Adalimumab	1894	525	181
Infliximab	2006	818	339
UC patients	716	176	52
Adalimumab	83	19	3
Infliximab	633	157	49
IBDU Patients	102	42	14
Adalimumab	24	12	2
Infliximab	78	30	12
Total patients	4718	1561	586
YOUR SITE - Patients with CD			

CD = Crohn's disease; IBDU, inflammatory bowel disease type unclassified; UC, ulcerative colitis.

Table 2 Key items to compare data from adult and paediatric patients with CD

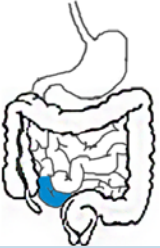


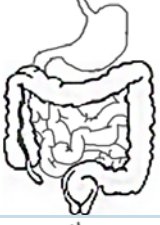
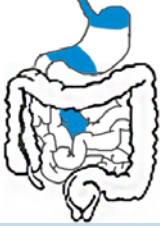
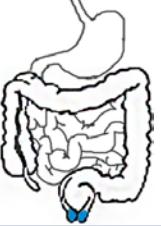
This table compares demographic data for adult and paediatric patients with CD treated with infliximab or adalimumab. The denominators differ when questions were not answered.

General patient characteristics	CD		YOUR SITE
	Adult	Paediatric	
Total number of patients	n=3900	n=579	
Gender: male (% , n/N)	47% (1837/3884)	63% (365/579)	
Age at diagnosis, years, median (IQR)	n=3739 27 (20, 39)	n=566 13 (10, 14)	
Age at initial treatment, years, median (IQR)	n=3894 36 (26, 49)	n=578 14 (12, 16)	
Time from diagnosis to treatment, years, median (IQR)	n=3739 4 (1, 12)	n=567 1 (1, 2)	

CD = Crohn's disease; IQR = interquartile range.

Table 3 Disease distribution

Crohn's disease can be classified in terms of severity – mild, moderate or severe – or by the Montreal classification, which proposes the maximum extent of involvement as the acute factor.⁷ This table describes the distribution of CD across audited adult and paediatric patients treated with adalimumab or infliximab.

Disease distribution		CD		YOUR SITE
		Adult (%, n/N)	Paediatric (%, n/N)	
		n=3900	n=579	
	Terminal ileum (L1)	27% (1035/3849)	12% (68/573)	
	Colonic (L2)	31% (1188/3849)	31% (176/573)	
	Ileocolonic (L3)	36% (1380/3849)	49% (283/573)	
	None of these	6% (239/3849)	8% (46/573)	
	Any part of the gut proximal to the terminal ileum (L4)	Yes= 45% (1312/2925)	Yes= 71% (352/495)	
	Perianal involvement	Yes= 31% (838/2688)	Yes= 47% (187/397)	

CD = Crohn's disease.

Table 4 Response to therapy

This table shows response to therapy in patients with CD who were treated with infliximab or adalimumab. Results are displayed at the 3-month follow-up timepoint. The Harvey–Bradshaw index (HBI) is used to quantify disease activity for adult patients with CD. The Paediatric Crohn's Disease Activity Index (PCDAI) is used to measure disease activity for paediatric patients with CD. The denominators change when dates of diagnosis for patients are missing.

CD patient group	Response to treatment* at 3-month follow-up (% , n/N)					
Time from diagnosis to initial treatment in years	<1	1–2	3–5	6–10	>10	Total
Adult	79% (121/154)	79% (115/145)	80% (89/112)	81% (86/106)	77% (159/207)	80% (570/715)
Paediatric	73% (35/48)	78% (52/67)	82% (18/22)	75% (9/12)	0% (0/0)	77% (114/149)
YOUR SITE						

*Decrease of >3 in Harvey–Bradshaw index for adult patients and >15 in Paediatric Crohn's Disease Activity Index for paediatric patients.

CD = Crohn's disease.

Table 5 Remission achieved

This table shows whether remission was achieved in patients with CD who were treated with infliximab or adalimumab. Results are displayed at the 3-month follow-up timepoint. As before, the HBI was used to quantify disease activity in adults with CD and the PCDAI to measure disease activity for paediatric patients with CD, and the denominators change when dates of diagnosis for patients are missing.

CD patient group	Remission* achieved when followed up at 3 months (% , n/N)					
Time from diagnosis to initial treatment in years	<1	1–2	3–5	6–10	>10	Total
Adult	68% (105/155)	67% (101/150)	72% (83/116)	71% (78/110)	64% (135/210)	68% (502/741)
Paediatric	59% (30/51)	66% (45/68)	68% (15/22)	75% (9/12)	0% (0/0)	55% (54/99)
YOUR SITE						

*Harvey–Bradshaw index (HBI) score <4 for adult patients and Paediatric Crohn's Disease Activity Index (PCDAI) score <10 for paediatric patients.

CD = Crohn's disease.

Table 6 Concomitant therapy

This table shows the percentage of all adult patients with CD on any immunosuppressant or steroid as concomitant therapy during their treatment with biological therapies. Data collected in PANTs have not been included in this analysis owing to time constraints but are expected to be included in the next report.

Type of concomitant therapy	Treatment time (% , n/N)		
	Initial treatment	3-month follow-up	12-month follow-up
Immunosuppressants*	53% (1644/3080)	48% (479/1000)	48% (192/404)
YOUR SITE			
Steroids†	27% (819/3080)	6% (64/1000)	5% (21/404)
YOUR SITE			

*Immunosuppressants include azathioprine, mercaptopurine and methotrexate.

†Steroids include budesonide, hydrocortisone, methylprednisolone and prednisolone.

Table 7 Analysis of results over time

This table compares some key results over time for adults with IBD included in the audit according to reporting timescales. A reduction in site participation between 2014 and 2015 was due to the reconfiguration of services across sites during the year.

Result	Audit period			
	June 2012 (12.09.11– 29.02.12)	August 2013 (01.03.12– 28.02.13)	September 2014 (01.03.13– 28.02.14)	September 2015 (01.03.14– 28.02.15)
Participation in the biological therapy audit				
Adult sites with data included in analysis (n)	78	94	143	134
Adult patients audited initiating biological therapies				
Patients with CD (n)	347	837	1252	1464
Patients with UC (n)	49	146	236	285
Patients with IBDU (n)	20	29	22	31
Total (n)	416	1012	1510	1780
Treatment time				
Time from diagnosis to initial treatment (years, median IQR)	n=413 4 (1, 11)	n=1007 4 (1, 11)	n=1475 4 (1, 12)	n=1657 4 (1, 10)
Adverse events				
Adverse events reported at initial treatment (% , n/N)	2% (9/416)	3% (26/1012)	3% (40/1510)	2% (42/1780)
Disease activity reported at initial treatment for adult patients				
HBI score, median (IQR)	n=226 6 (0, 10)	n=421 9 (6, 12)	n=710 8 (4, 11)	n=925 7 (4, 10)*
SCCAI score, median (IQR)	n=44 6 (0, 9)	n=90 9 (6, 11)	n=99 8 (6, 11)	n=129 9 (6, 12)
Adult patients with CD on concomitant therapies at initial treatment				
Immunosuppressants (% , n/N)	54% (189/347)	58% (482/837)	38% (473/1252)	34% (500/1464)*
Steroids (% , n/N)	27% (93/347)	27% (222/837)	22% (274/1252)	16% (230/1464)

*p<0.001.

CD = Crohn's disease; HBI = Harvey–Bradshaw index; IBDU = inflammatory bowel disease type unclassified; IQR = interquartile range; SCCAI = Simple Clinical Colitis Activity Index; UC = ulcerative colitis.

Table 8 National comparison of key results for adults with CD

This table depicts national variation in the results of the biological therapy audit between England, Northern Ireland, Scotland and Wales. It only includes sites that submitted enough data to be included in the national analysis. A full list of participating and non-participating sites can be found in **section 6, p 64** of this report.

Result	Country			
	England	Northern Ireland	Scotland	Wales
Sites participating in the audit (% , n/n)	84% (141/167)	75% (9/12)	52% (11/21)	44% (7/16)
Patients audited (n)	3531	90	126	153
Time from diagnosis to initial treatment (years, median (IQR))	n=3379 4 (1, 12)	n=90 4 (1, 10)	n=119 5 (1, 12)	n=151 4 (1, 12)
Patients with an adverse reaction recorded during initial treatment (% , n/n)	3% (97/3531)	2% (2/90)	2% (3/126)	3% (4/153)
Disease severity (HBI) at initial treatment, median (IQR)	n=2082 8 (4, 11)	n=27 9 (5, 11)	n=66 6 (3, 9)	n=109 7 (4, 10)
Patients with follow-up recorded at 3 months (% , n/N)	35% (1238/3531)	11% (10/90)	31% (39/126)	37% (56/153)
Patients on biological therapy who were appropriately prescribed anti-TNF α in compliance with NICE technology appraisal 187 ² criterion 1.1 (% , n/N)	46% (949/2082)	56% (15/27)	33% (22/66)	46% (50/109)

HBI = Harvey–Bradshaw index; IQR = interquartile range; TNF α = tumour necrosis factor alpha.

Tables 9 and 10 Biological therapies audit case ascertainment

These two tables compare results as reported in the *National audit of inflammatory bowel disease (IBD) service provision (September 2014)*.⁸ Sites participating in this audit were asked to report on the number of patients with IBD who had newly started on infliximab or adalimumab between 1 January 2013 and 31 December 2013. Sites were able to indicate whether the figure was an estimate or was taken from an existing database of patients. The number of patients reported as newly started on biological therapy in the organisational audit was then compared with the actual number of patients audited in the biological therapy audit for the same time period and used to produce a case ascertainment figure.

Patients newly started on adalimumab	National	YOUR SITE
Patients with IBD who were newly started on adalimumab between 1 January 2013 and 31 December 2013, as reported in organisational audit (September 2014) ⁸ (n)	2692 (reported by 171 sites)	
Newly started patients – estimated (n)	949 (reported by 69 sites)	
Newly started patients – taken from a database (n)	1728 (reported by 101 sites)	
Newly started patients – taken from unknown source (n)	15 (reported by 1 site)	
Patients with IBD entered into biological therapies audit who were newly started on adalimumab between 1 January 2013 and 31 December 2013 (n)	566	
Case ascertainment rate (%)	21%	

IBD = inflammatory bowel disease.

Patients newly started on infliximab	National	YOUR SITE
Patients with IBD who were newly started on infliximab between 1 January 2013 and 31 December 2013, as reported in organisational audit (September 2014) ⁸ (n)	3400 (reported by 170 sites)	
Newly started patients – estimated (n)	1330 (reported by 68 sites)	
Newly started patients – taken from a database (n)	2048 (reported by 101 sites)	
Newly started patients – taken from unknown source (n)	22 (reported by 1 site)	
Number of patients with IBD who were newly started on infliximab between 1 January 2013 and 31 December 2013, as entered into biological therapies audit (n)	793	
Case ascertainment rate (%)	23%	

IBD = inflammatory bowel disease.

Audit objectives

Safety

Table 11 Adverse events

This table shows the percentage of all adult patients for whom an adverse reaction was recorded during their treatment, by type of reaction.

Adverse event (% , n)	Initial treatment (n=4718)	3-month follow-up (n=1516)	12-month follow-up (n=586)
Adverse event recorded			
Yes=	3% (117)	8% (126)	6% (33)
Abdominal pain	0.04% (2)	0.3% (5)	0.2% (1)
Alopecia	0% (0)	0.1% (1)	0.2% (1)
Angioedema of upper airway	0.06% (3)	0.1% (2)	0.2% (1)
Arthralgia	0.3% (13)	0.6% (10)	0% (0)
Blood abnormality	0.02% (1)	0.4% (7)	0% (0)
Bronchospasm (cough/wheeze/dyspnoea)	0.3% (13)	0.5% (8)	0.5% (3)
Cardiac failure	0% (0)	0% (0)	0% (0)
Chest pain	0.1% (5)	0.1% (1)	0% (0)
Chills	0.04% (2)	0.1% (1)	0.9% (5)
Confirmed demyelination	0.04% (2)	0% (0)	0% (0)
Death	0% (0)	0.1% (1)	0% (0)
Difficulty breathing	0% (0)	0.2% (3)	0% (0)
Dizziness	0.3% (12)	0.4% (6)	0% (0)
Fatigue	0.1% (5)	0.3% (5)	0.2% (1)
Fever	0.2% (9)	0.2% (3)	0% (0)
Flushing	0.3% (16)	0.7% (11)	0.2% (1)
Headache	0.4% (21)	0.4% (6)	0.5% (3)
Hypotension	0.1% (5)	0.3% (4)	0% (0)
Infection	0.1% (4)	2% (36)	2% (11)
Injection site reaction	0.1% (4)	0.2% (3)	0% (0)
Itching	0.3% (12)	0.3% (5)	0.2% (1)
Limb weakness	0.04% (2)	0.1% (1)	0% (0)
Malignancy	0% (0)	0% (0)	0% (0)
Nausea	0.4% (17)	0.7% (11)	0.2% (1)
Panic attacks	0.1% (5)	0.1% (1)	0% (0)
Rash	0.4% (18)	1% (21)	0.3% (2)
Serum sickness-like reaction	0% (0)	0% (0)	0% (0)
Urticaria	0.04% (2)	0.3% (4)	0% (0)
Other	0.7% (32)	2% (24)	2% (10)

Efficacy

Disease activity for adult patients at the time of initial treatment was compared with that at the follow-up nearest to 3 and 12 months from the date of the initial treatment. Follow-up data include only those patients who had an initial treatment.

Table 12 Disease activity – CD

When severity of CD is classified by HBI, a score <5 is considered to be clinical remission and >16 is considered to be severe disease.

HBI score	Initial treatment	3-month follow-up	12-month follow-up
Adalimumab, median (IQR)	n=1081 8 (4, 11)	n=264 3 (1, 6)	n=95 3 (1, 5)
Infliximab, median (IQR)	n=1201 7 (4, 10)	n=524 2 (1, 5)	n=215 2 (0, 4)
Total	n=2282 8 (4, 10)	n=788 3 (1, 6)	n=310 2 (0, 5)
YOUR SITE			

HBI = Harvey–Bradshaw index; IQR = interquartile range.

Table 13 Disease activity – UC

When severity of UC is classified by SCCAI, a score of <3 is considered to be remission and >13 is considered to be severe disease.

SCCAI score	Initial treatment	3-month follow-up	12-month follow-up
Adalimumab, median (IQR)	n=41 7 (6, 8)	n=9 3 (1, 6)	n=2
Infliximab, median (IQR)	n=321 9 (6, 11)	n=77 2 (0, 6)	n=18 3 (1, 4)
Total	n=362 9 (6, 11)	n=86 2 (0, 5)	n=20 3 (1, 4)

IQR = interquartile range; SCCAI = Simple Clinical Colitis Activity Index.

Table 14 Surgery

This table shows combined surgical activity for patients with CD, UC and IBDU recorded in the 6 months before and after treatment with biological therapies. Further information about the surgical data collected in the biological therapies audit can be found on **p 60** of this report.

Surgical activity	Adult (%, n/N)	Paediatric (%, n/N)
Pre-treatment surgery recorded		
Yes	23% (1066/4718)	9% (65/696)
Patients with surgery recorded 6 months before starting biological therapies	5% (244/4718)	6% (39/696)
Patients with surgery recorded 6 months after starting biological therapies	3% (157/4718)	5% (31/696)

Appropriateness of prescribing anti-TNF α

Detailed information about the NICE guidance and recommendations for use of biological therapies in patients with IBD in the UK can be found in **section 4, p 30** of this report. In Tables 15 and 16, NICE criterion 1.1 from technology appraisal 187² and criterion 1.1 from technology appraisal 329³ have been used to assess the appropriateness of prescribing biological therapy.

Table 15 Compliance with NICE technology appraisal 187

This table shows compliance with criterion 1.1 of NICE technology appraisal 187² in adult patients with CD. Patients with no recorded HBI were excluded from this analysis.

NICE technology appraisal 187	National CD data, % (n/N)	YOUR SITE
Criterion 1.1 Infliximab and adalimumab are recommended as treatment options for adults with severe active CD if (a) the disease has not responded to conventional therapy or (b) the person is intolerant of or have contraindications to conventional therapy (mercaptopurine, azathioprine, methotrexate, prednisolone, budesonide, methylprednisolone or hydrocortisone)		
Patients with CD on biological therapy with HBI score ≥ 8 before starting anti-TNF α treatment	51% (1159/2282)	
Patients with CD who were treated with conventional therapy at time of or prior to starting biological therapy	86% (1951/2282)	
Patients with CD on biological therapy who were appropriately prescribed anti-TNF α treatment in compliance with criterion 1.1 of NICE technology appraisal 187	45% (1035/2282)	

CD = Crohn's disease; HBI = Harvey-Bradshaw index; NICE = National Institute for Health and Clinical Excellence; TNF α = tumour necrosis factor alpha.

Although compliance with NICE guidance seems to be low for patients with CD, many patients are likely to have had the prerequisite disease activity before starting biological therapy. Many patients will have been treated with corticosteroids, resulting in the observed values.

Table 16 Compliance with NICE technology appraisal 329

This table shows compliance with criterion 1.1 of NICE technology appraisal 329³ in adult patients with UC. Patients with no recorded SCCAI were excluded from this analysis.

NICE technology appraisal 329	National UC data (% n/N)
Criterion 1.1 Infliximab, Adalimumab and golimumab are recommended as treatment options for adults with moderate to severe active UC (a) whose disease has responded inadequately to conventional therapy or (b) are intolerant of or have contraindications to conventional therapy (mercaptopurine, azathioprine, methotrexate, prednisolone, budesonide, methylprednisolone or hydrocortisone)	
Patients on biological therapy with SCCAI score ≥ 5 before starting anti-TNF α treatment	87% (276/318)
Patients who were treated with conventional therapy at time of or prior to starting biological therapy	95% (301/318)
Patients on biological therapy who were appropriately prescribed anti-TNF α therapy in compliance with criterion 1.1 of NICE technology appraisal 329	82% (262/318)

SCCAI = Simple Clinical Colitis Activity Index; NICE = National Institute for Health and Care Excellence; TNF α = tumour necrosis factor alpha; UC = ulcerative colitis.

Patient-reported outcome measures

Table 17 PROMs questionnaire for IBD (IBD-PROM)

This table gives completion rates and results of the IBD-PROM questionnaires used in the biological therapies audit – the EQ-5D⁹ and Crohn's and ulcerative colitis questionnaire (CUCQ)-12¹⁰ – for all adult patients calculated. Total EQ-5D scores range from 0 (worst health / death) to 1 (best health), with an increase in score denoting improved health. Total CUCQ-12 scores range from 0 (best health) to 168 (poor health), with each question scored between 0 (best) and 14 (poor). Further information about the EQ-5D and CUCQ-12 can be found on pp 62–63 of this report.

IBD-PROM	Initial treatment	3-month follow-up	12-month follow-up
Patients with completed IBD-PROM (%, n/N)	30% (1416/4718)	25% (384/1561)	22% (129/586)
YOUR SITE number of patients with IBD-PROM completed			
Patients with EQ-5D data completed, (%, n/N)	97% (1367/1416)	94% (361/384)	44% (57/129)
EQ-5D score, median (IQR)	0.76 (0.66, 0.85)	0.80 (0.73, 1)	0.80 (0.69, 1)
Patients with CUCQ-12 data completed (%, n/N)	89% (1256/1416)	87% (332/384)	87% (112/129)
CUCQ-12 score, median (IQR)	68 (39, 100)	34 (14, 60)	27 (10, 49)

CUCQ = Crohn's and ulcerative colitis questionnaire; IBD = inflammatory bowel disease; IQR = interquartile range; PROMs = patient-reported outcome measures.

3: Background information

The burden of inflammatory bowel disease

The inflammatory bowel diseases UC and CD are lifelong inflammatory conditions that involve the gastrointestinal tract. The incidence of IBD has risen dramatically in recent decades and continues to do so; it is reported to be as high as 24.3 and 12.7 per 100,000 persons per year in Europe for UC and CD, respectively. The reported prevalence in Europe is as high as 505 and 322 per 100,000 persons for UC and CD, respectively.¹¹ Inflammatory bowel disease first presents most commonly in the second and third decades of life, but much of the recent increase has been observed in childhood, notably with CD in children increasing threefold in 30 years. Between 20% and 30% of patients with UC will require colectomy, and about 50–70% of patients with CD require surgery. The main symptoms of both conditions include diarrhoea, abdominal pain, anaemia and an overwhelming sense of fatigue, with, for some patients, associated features such as arthritis, anal disease, fistulae, abscesses and skin problems, which can also contribute to poor quality of life. In addition, IBD has wide-ranging effects on growth and pubertal development, psychological health, education and employment, family life, fertility and pregnancy. Effective multidisciplinary care can attenuate relapse, prolong remission, treat complications and improve quality of life.

The UK IBD audit

The UK IBD audit seeks to improve the quality and safety of care for all patients with IBD throughout the UK by auditing individual patient care and the provision and organisation of IBD service resources and by reporting on inpatient experience and PROMs. The biological therapies audit is one element of the wider UK IBD audit.

This report follows the national reports published in 2012, 2013 and 2014. It builds on the previous reports as a continuous audit with increasing rates of participation, and it provides further evidence about the safety, efficacy and appropriate use of biological therapies. Furthermore, it enables participating sites to benchmark their performance against national data. All data should be considered within the context of the actual number of treatments.

Further information on the work of the UK IBD audit project can be accessed via the IBD page of the RCP website (www.rcplondon.ac.uk/ibd).

The benefits of the biological therapies audit

The biological therapies audit is an electronic register of patients receiving treatment and enables IBD teams to:

- monitor the disease activity of patients over the course of their treatment with biological drugs
- monitor and encourage improved management at patient and service levels, data on adverse events, dose escalation and treatment regimens
- capture the views of patients locally on their quality of life at intervals throughout their treatment
- benchmark local results against national-level data
- generate individual patient summaries
- generate letters detailing treatment plans
- assess compliance with the **IBD standards** and **NICE quality standard 81**.^{1,4}

4: The biological therapies audit

What is the role of biological therapy in the treatment of IBD?

Infliximab

Infliximab (Remicade®) is a chimeric anti-TNF α monoclonal antibody with potent anti-inflammatory effects that are possibly dependent on apoptosis of inflammatory cells. Controlled trials have demonstrated efficacy in both active and fistulating CD. Infliximab is typically administered via an intravenous infusion during a hospital appointment under the supervision of a suitably qualified health professional.

Adalimumab

Adalimumab (Humira™) is a recombinant human immunoglobulin (IgG1) monoclonal antibody containing only human peptide sequences. Adalimumab is typically delivered via a self-administered injection. Patients are provided with a home supply of the medication and, following tuition and close monitoring, are able to manage their own treatment with regular medical follow-up.

Approval in the UK

In **multi-technology appraisal 187** for patients with CD,² NICE made the following recommendations:

- Infliximab and adalimumab may be used within their licensed indications as treatment options for adults with severe active CD, whose disease has not responded to conventional therapy (including immunosuppressive and/or corticosteroid treatments).
- Infliximab has been recommended for the treatment of active fistulating CD in patients whose disease has not responded to conventional therapy or have medical contraindications for such therapies.
- Infliximab is recommended for the treatment of people aged 6–17 years with severe, active CD, whose disease has not responded to conventional therapy (including corticosteroids, immunomodulators and primary nutrition therapy) or have contraindications to conventional therapy.
- Infliximab and adalimumab should be given as a planned course of treatment until treatment failure (including the need for surgery) or until 12 months after the start of treatment, whichever is shorter. Patients' disease should then be reassessed to determine whether ongoing treatment is still clinically appropriate.

In **multi-technology appraisal 329** for patients with UC,³ NICE made the following recommendations:

- Infliximab and adalimumab may be used within their licensed indications as treatment for moderate to severe active UC in adults whose disease has responded inadequately to conventional therapy or who cannot tolerate or have medical contraindications for such therapies.
- Infliximab has been recommended for treating severely active UC in children and young people aged 6–17 years whose disease has responded inadequately to conventional therapy or who cannot tolerate or have medical contraindications for such therapies.
- Infliximab or adalimumab should be given as a planned course of treatment until treatment failure (including the need for surgery) or until 12 months after the start of treatment, whichever occurs first. Patients' disease should then be reassessed to determine whether ongoing treatment is still clinically appropriate.

In **technology appraisal 163**,¹² NICE made the following recommendation:

- Infliximab as an option for the treatment of acute exacerbations of severely active UC only in patients for whom ciclosporin is contraindicated or clinically inappropriate.

Data entry into the biological therapies audit

Data entry takes place in the form of 'submissions' to a web-based data collection tool. A submission refers to data entered in any of the following categories: patient demographics, IBD details, initial treatment, follow-up treatment and IBD-related surgery. Once all mandatory fields are completed within a category, the data are locked to form a completed submission, and they are then suitable for inclusion in national findings. Only locked data can be viewed by the UK IBD audit project team. The full audit dataset is available from the RCP website (www.rcplondon.ac.uk/biologics).

Patient demographics category

Patients are identified prospectively when the decision to treat using biological therapies is made by a clinician. The demographic details of this patient are entered using the web tool; this includes a number of patient identifiers that are pseudonymised at the point of data entry and are visible only to the participating site. Details of the patient's consultant and GP can also be entered, although this is not mandatory for the audit.

Disease details category

This section requires sites to provide details of the patient's IBD history, including the extent of their disease, any related comorbid conditions and details of any surgical procedures undertaken prior to the initiation of biological therapies.

Initial treatment category

This section collects details of the initial or baseline treatment. The site indicates whether the patient has CD, UC or IBDU and whether they are being treated with adalimumab or infliximab. The system then generates appropriate questions for these options. Information is collected about pre-treatment investigations and screening up to the point of completion or abandonment of the treatment, with details of any treatment reactions that occur.

Follow-up treatment category

Each follow-up treatment that is entered must relate to a previously entered initial treatment submission. An unlimited number of follow-up treatments can be completed to allow outgoing data collection as the patient continues to be treated with biological therapies. The outcome of each follow-up treatment – that is, whether treatment will continue or be stopped – must be provided. Details of any adverse events are recorded for each follow-up treatment.

IBD-related surgery category

Details of IBD-related surgery can be added to the web tool at any time. A prompt to update this section of the web tool appears at the conclusion of all initial and follow-up treatment submissions. This allows identification of any escalation of treatment that is required while a patient is being treated with biological therapy.

PROMs category

Data on PROMs are collected at initial treatment and can then be recorded at any additional follow-up. For the purpose of the audit, the PROMs completed at 3- and 12-month follow-up treatments are of interest. For further information about PROMs data, see **pp 62–63**.

Continued development of the biological therapies audit web tool

The biological therapies audit web tool has been continually updated and developed in line with the requirements identified through feedback from participants and to reflect emerging evidence. Some examples of the adaptations made to date are summarised below.

Biosimilars

From March 2015, to reflect emerging evidence and changing practice, the biological therapies audit was expanded to allow auditing of patients who are newly started on biosimilar versions of the biological drugs.

Existing patients

This was one of the first adaptations of the system and allowed the inclusion of data for patients already established on biological therapy in addition to those newly started on these drugs. This allowed sites to begin to build their own local registers of patients being treated with biological therapies. This report does not contain analyses of data entered for patients already established on biological therapy; data for these patients are collected only by those sites that wish to use the data at a local level.

Reporting functions

Sites can produce patient and treatment summary reports when required; these are summarised briefly below.

Patient summary report

This is a printable summary of all treatments provided for a specific patient over the course of their management; details of any adverse events, acute reactions and relevant surgery are listed. A graphical display of the patient's disease severity scores over time allows a simple visual representation of the success/failure of treatment to encourage action when required. The patient summary can be filed in the patient's case notes or provided with an accompanying letter to the patient's GP.

Treatment summary report

This is a printable summary of any isolated initial or follow-up treatment; again, this can be filed in the case notes to avoid duplication of effort or included in correspondence with a GP to inform them of the treatment provided to their patient on any particular occasion.

Data import function

The 'Import data' function allows users to upload data held in other spreadsheets or registers directly into the biological therapy audit web tool through a simple template. This avoids duplication of both effort and data entry on sites.

Reduction of mandatory fields

Following feedback from users regarding the length of time taken to enter submissions onto the web tool, the number of mandatory fields is under constant review and is regularly reduced to make the process of entering and locking data faster and simpler.

Download function

Users are able to download their previous site reports, printable versions of the audit tools, help notes and a user guide to assist them with data entry.

Data export function

Users are able to export all data that they have submitted since the start of the audit directly from the audit web tool. Data are exported in the form of an editable Excel file.

Dashboard

The dashboard is the latest development for the web tool. It is split into various sections, each giving sites a glance at their activity on the audit to date. Fig 2 outlines the functions available on the dashboard.

Fig 2 Functions of the biological therapy audit dashboard

Patient summary

This gives an overview of how many patients have been added to the web tool by the site. It also flags up any patients for whom a follow-up treatment has not been recorded in the last 90 days.

Patients initiating biologics graph

This shows how many patients the site has started on each of the different biological therapies.



Performance summary

This gives the site an idea of how well they are performing in terms of locking their complete submissions. A happy, neutral or unhappy face is displayed depending on the percentage of locked submissions.

Submissions summary

This pie chart displays locked versus unlocked submissions. When the link is clicked, the site can see all of their unlocked submissions.

Activity over time

This gives sites an overview of submissions entered in each category over time, including the year of data entry.

System security of the biological therapies audit web tool

The document *Biological therapies audit system and hosted server security details* outlines the system security information provided to all sites invited to participate in the audit and is available on the RCP website (www.rcplondon.ac.uk/biologics).¹³ The document gives an overview of the security measures in place, while providing assurance that security procedures designed by Microsoft and other industry-standard bodies have been followed. The contracted system developer also implemented the recommended procedures contained within the NHS document *Securing web infrastructure and supporting services good practice guideline*.¹⁴

Further details can be found on the following: physical data centre (location, security, admission control, climatisation, electricity and fire protection), operating system (version, user access, security, encryption, updates and patches, and backups), database software (version, user access and encryption) and application software (source control, user access and encryption).

The purpose of collecting patient-identifiable data was to make the system useful for staff at a local site level by enabling full monitoring and interpretation of the data for the purpose of immediate local service improvement and patient care. Patient-identifiable data can be viewed only by registered members of the local team, whose access to the site will have been approved via the local clinical lead (nearly always a consultant gastroenterologist). Sites using the web tool cannot view data entered at other participating sites. The UK IBD audit project team have administrative control to analyse anonymised data only and are not able to view any patient-identifiable information.

In accordance with the principles of the Data Protection Act, sites participating in the biological therapies audit are reminded that patients should be informed of the use of their data by means of the information leaflets and posters provided by the UK IBD audit project team.

5: Full national audit results tables

Crohn's disease details

CD: disease details	Frequency (% , n)			
	Infliximab		Adalimumab	
	National (n=2006)	YOUR SITE	National (n=1894)	YOUR SITE
Diagnosis				
Maximal disease distribution at the time of decision to initiate biological therapy, as defined by the Montreal classification	(n=1973)		(n=1876)	
Terminal ileum (L1)	25% (501)		29% (534)	
Colonic (L2)	34% (671)		28% (517)	
Ileocolonic (L3)	34% (678)		37% (702)	
None of these	6% (123)		7% (123)	
Any part of the gut proximal to the terminal ileum (L4)	(n=1438)		(n=1487)	
Yes	42% (604)		48% (708)	
Perianal involvement?	(n=1357)		(n=1331)	
Yes	36% (484)		27% (354)	
Time between date of diagnosis and date of initial treatment	(n=1912)		(n=1823)	
<1 year	26% (497)		18% (330)	
1–2 years	18% (351)		20% (367)	
3–5 years	15% (287)		16% (294)	
6–10 years	15% (287)		17% (314)	
>10 years	26% (490)		28% (518)	

CD = Crohn's disease.

Crohn's disease initial treatment

CD: initial treatment	Frequency (% , n)			
	Infliximab		Adalimumab	
	National (n=2006)	YOUR SITE	National (n=1894)	YOUR SITE
Consent				
Was informed consent to receive anti-TNFα treatment taken from this patient?				
Yes	98% (1973)		99% (1872)	
No	2% (33)		1% (22)	
If yes, was this verbal or written?	(n=1973)		(n=1872)	
Verbal	63% (1247)		63% (1175)	
Written	37% (726)		37% (697)	
Treatment details				
Time between date of decision to start and date of initial treatment (first loading dose)				
Median (IQR) time (days)	16 (6, 36)		21 (10, 42)	
What was the clinical indication for this treatment?	(n=1926)		(n=1851)	
Severe perianal CD	15% (297)		9% (157)	
Active luminal CD	81% (1560)		88% (1625)	
Fistulating CD	1% (22)		0.5% (10)	
Other clinical indication	2% (29)		1% (21)	
Not known	1% (19)		2% (38)	
Dose given at this infusion (mg/kg)	(n=1594)			
5	100% (1590)		NA	NA
10	0.3% (4)		NA	NA
Duration of infusion (mins)	(n=1105)			
30	0.3% (3)		NA	NA
60	0.7% (8)		NA	NA
120	95% (1054)		NA	NA
180	3% (37)		NA	NA
240	0.2% (2)		NA	NA
Other	0.1% (1)		NA	NA
Infusion completion outcome	(n=1528)			
Completed successfully at prescribed rate	98% (1492)		NA	NA
Completed successfully at lower rate	0.9% (13)		NA	NA
Restart infusion at lower rate and discontinued	0.2% (3)		NA	NA
Infusion discontinued and not restarted	1% (19)		NA	NA
Other	0.1% (1)		NA	NA

CD = Crohn's disease; IQR = interquartile range; NA = not applicable; TNF α = tumour necrosis factor alpha.

CD: initial treatment	Frequency (% , n)			
	Infliximab		Adalimumab	
	National (n=2006)	YOUR SITE	National (n=1894)	YOUR SITE
Treatment details continued				
Induction dose (mg)		(n=1870)		
160/80	NA	NA	80% (1492)	
80/40	NA	NA	18% (342)	
Other	NA	NA	2% (36)	
Planned maintenance dose (mg)		(n=1662)		
40 mg every other week	NA	NA	95% (1573)	
40 mg every week	NA	NA	5% (74)	
Other	NA	NA	0.9% (15)	
Were any adverse events recorded for this treatment?				
Yes	3% (58)		3% (48)	
Which adverse events? (more than one may have been selected)				
Abdominal pain	0.1% (1)		0.1% (1)	
Angioedema of upper airway	0.1% (2)		0.1% (1)	
Arthralgia	0.5% (9)		0.2% (3)	
Blood abnormality	0% (0)		0.1% (1)	
Bronchospasm (cough/wheeze/dyspnoea)	0.5% (10)		0.1% (1)	
Chest pain	0.1% (3)		0.1% (1)	
Chills	0% (0)		0.1% (2)	
Confirmed demyelination	0% (0)		0.1% (2)	
Dizziness	0.2% (4)		0.3% (5)	
Fatigue	0.1% (2)		0.1% (2)	
Fever	0.3% (6)		0.1% (2)	
Flushing	0.6% (12)		0% (0)	
Headache	0.6% (13)		0.3% (6)	
Hypotension	0.1% (2)		0.1% (1)	
Infection	0.1% (1)		0.2% (3)	
Injection site reaction	0% (0)		0.2% (4)	
Itching	0.4% (8)		0.2% (3)	
Nausea	0.3% (6)		0.5% (9)	
Panic attacks	0.1% (1)		0% (0)	
Rash	0.5% (9)		0.5% (9)	
Serum sickness-like reaction	0% (0)		0% (0)	
Urticaria	0.1% (2)		0% (0)	
Other	0.4% (8)		0.2% (4)	

CD = Crohn's disease; NA = not applicable.

CD: initial treatment	Frequency (% , n)			
	Infliximab		Adalimumab	
	National (n=2006)	YOUR SITE	National (n=1894)	YOUR SITE
Treatment details continued				
Is the patient receiving any concomitant therapies for the management of IBD at the time of this treatment?	(n=1528)		(n=1552)	
Yes	75% (1140)		72% (1120)	
If yes, indicate which concomitant therapies (more than one may have been selected)				
Allopurinol	0.3% (4)		0.1% (1)	
Azathioprine/mercaptopurine	51% (772)		45% (701)	
5-aminosalicylic acid	20% (300)		17% (267)	
Antibiotics	2% (28)		1% (16)	
Ciclosporin	0.1% (2)		0% (0)	
Dietary therapy	3% (42)		2% (36)	
Methotrexate	4% (62)		7% (113)	
Mycophenolate	0.1% (2)		0% (0)	
Steroids	27% (412)		26% (407)	
Other	1% (16)		2% (25)	
Has the patient failed to respond or are they intolerant to immunosuppressive drugs / corticosteroids?	(n=2006)		(n=1894)	
Yes	62% (1250)		69% (1313)	
If yes, indicate which previous therapies (more than one may have been selected)				
Allopurinol	0.1% (2)		0% (0)	
Azathioprine/mercaptopurine	42% (835)		49% (933)	
5-aminosalicylic acid	16% (324)		17% (326)	
Antibiotics	7% (145)		6% (104)	
Anti-TNF α	4% (82)		10% (183)	
Ciclosporin	0.2% (4)		0.1% (2)	
Dietary therapy	5% (100)		4% (84)	
Methotrexate	6% (115)		9% (162)	
Mycophenolate	0.1% (3)		0.1% (2)	
Steroids	30% (606)		29% (547)	
Tacrolimus	0.1% (1)		0.1% (1)	
Topical	0% (0)		0.1% (1)	
Ustekinumab	0% (0)		0.1% (1)	
Other	0.7% (14)		0.8% (16)	

CD = Crohn's disease; IBD = inflammatory bowel disease; TNF α = tumour necrosis factor alpha.

CD: initial treatment	Frequency (% , n)			
	Infliximab		Adalimumab	
	National (n=2006)	YOUR SITE	National (n=1894)	YOUR SITE
Disease severity score				
Severity of disease	(n=1107)		(n=1160)	
Mild	7% (75)		6% (67)	
Moderate	43% (480)		45% (526)	
Severe	50% (552)		49% (567)	

CD = Crohn's disease.

Crohn's disease follow-up treatment at 3 months

CD: follow-up treatment at 3 months	Frequency (% , n)			
	Infliximab		Adalimumab	
	National (n=818)	YOUR SITE	National (n=525)	YOUR SITE
Follow-up treatment details				
Infliximab dose given (mg/kg)	(n=803)			
5	99% (795)		NA	NA
10	0.4% (3)		NA	NA
Other	0.6% (5)		NA	NA
Review of treatment plan				
Continue treatment	94% (772)		89% (467)	
Stop treatment	6% (46)		11% (58)	
If treatment was stopped, what were the reasons for stopping?	(n=46)		(n=58)	
Treatment effective and discontinued	2% (1)		0% (0)	
Loss of response	11% (5)		17% (10)	
Poor response	37% (17)		31% (18)	
Side effects / adverse events	33% (15)		41% (24)	
Patient became pregnant since initiating anti-TNF α treatment	0% (0)		2% (1)	
Patient choice	11% (5)		5% (3)	
Other	7% (3)		3% (2)	
If continuing adalimumab treatment, planned continued treatment frequency?	(n=453)			
Every week	NA	NA	5% (21)	
Every other week	NA	NA	95% (432)	
If continuing adalimumab treatment, planned continued treatment dose (mg)	(n=467)			
40	NA	NA	99% (461)	
80	NA	NA	1% (6)	
Did the patient report complete compliance with the maintenance regime since the last adalimumab review?	(n=440)			
Yes	NA	NA	95% (419)	
No	NA	NA	5% (21)	
If incomplete compliance, state reason (more than one may have been selected)	(n=21)			
Number of missed doses	NA	NA	14% (3)	
Increased interval between doses	NA	NA	14% (3)	
Patient missed out some treatment weeks	NA	NA	38% (8)	
Patient stopped treatment	NA	NA	19% (4)	
Compliance affected due to interventions in treatment	NA	NA	10% (2)	
Other compliance difference	NA	NA	10% (2)	

CD = Crohn's disease; NA = not applicable; TNF α = tumour necrosis factor alpha.

CD: follow-up treatment at 3 months	Frequency (% , n)			
	Infliximab		Adalimumab	
	National (n=818)	YOUR SITE	National (n=525)	YOUR SITE
Follow-up treatment details continued				
Were there any adverse events since the last review?				
Yes	6% (51)		11% (57)	
What adverse events? (more than one may have been selected)				
Abdominal pain	0.1% (1)		0.4% (2)	
Alopecia	0% (0)		0.2% (1)	
Angioedema of upper airway	0.1% (1)		0% (0)	
Arthralgia	0.6% (5)		1% (5)	
Blood abnormality	0.2% (2)		0.8% (4)	
Bronchospasm (cough/wheeze/dyspnoea)	0.4% (3)		0.2% (1)	
Cardiac failure	0.1% (1)		0% (0)	
Chest pain	0.1% (1)		0% (0)	
Chills	0.1% (1)		0% (0)	
Death	0.1% (1)		0% (0)	
Difficulty breathing	0.2% (2)		0.2% (1)	
Dizziness	0.4% (3)		0.2% (1)	
Fatigue	0.1% (1)		0.6% (3)	
Fever	0.1% (1)		0.4% (2)	
Flushing	0.6% (5)		0.2% (1)	
Headache	0.5% (4)		0% (0)	
Hypotension	0.1% (1)		0.2% (1)	
Infection	2% (13)		0.2% (1)	
Injection site reaction	0% (0)		0.6% (3)	
Itching	0.1% (1)		0.6% (3)	
Nausea	0.6% (5)		1% (5)	
Rash	0.9% (7)		3% (13)	
Urticaria	0% (0)		0.6% (3)	
Other	2% (12)		2% (10)	

CD = Crohn's disease; NA = not applicable.

CD: follow-up treatment at 3 months	Frequency (% , n)			
	Infliximab		Adalimumab	
	National (n=818)	YOUR SITE	National (n=525)	YOUR SITE
Follow-up treatment details continued				
Is the patient currently receiving any other therapies for the management of IBD?	(n=554)		(n=446)	
Yes	63% (351)		55% (246)	
If yes, indicate which other therapies (more than one may have been selected)				
Allopurinol	0.2% (1)		0% (0)	
Azathioprine/mercaptopurine	50% (277)		35% (156)	
Methotrexate	4% (20)		6% (27)	
Steroids	4% (23)		9% (41)	
5-aminosalicylic acid	17% (92)		10% (46)	
Antibiotics	0% (0)		0.4% (2)	
Dietary therapy	1% (6)		2% (9)	
Topical	0% (0)		0.2% (1)	
Other	0.7% (4)		3% (13)	
Disease severity score				
Severity of disease	(n=363)		(n=321)	
Mild	54% (195)		48% (153)	
Moderate	29% (104)		37% (120)	
Severe	18% (64)		15% (48)	

CD = Crohn's disease; IBD = inflammatory bowel disease; NA = not applicable.

Crohn's disease follow-up treatment at 12 months

CD: follow-up treatment at 12 months	Frequency (% , n)			
	Infliximab		Adalimumab	
	National (n=339)	YOUR SITE	National (n=181)	YOUR SITE
Follow-up treatment details				
Infliximab dose given at this treatment (mg/kg)	(n=334)			
5	97% (323)		NA	NA
10	3% (9)		NA	NA
Other	0.6% (2)		NA	NA
Review of treatment plan				
Continue treatment	93% (314)		88% (159)	
Stop treatment	7% (25)		12% (22)	
If treatment was stopped, what were the reasons for stopping?	(n=25)		(n=22)	
Loss of response	16% (4)		9% (2)	
Treatment effective and discontinued	40% (10)		27% (6)	
Side effects / adverse events	20% (5)		27% (6)	
Funding	4% (1)		5% (1)	
Poor response	4% (1)		9% (2)	
Patient choice	4% (1)		9% (2)	
Patient became pregnant since initiating anti-TNF α treatment	4% (1)		9% (2)	
Other	4% (1)		5% (1)	
If continuing adalimumab treatment, planned continued treatment frequency	(n=154)			
Every week	NA	NA	12% (19)	
Every other week	NA	NA	86% (133)	
Other	NA	NA	1% (2)	
If continuing adalimumab treatment, planned continued treatment dose (mg)	(n=158)			
20/25	NA	NA	0.6% (1)	
30	NA	NA	0.6% (1)	
40	NA	NA	96% (152)	
80	NA	NA	3% (4)	
Did the patient report complete compliance with the maintenance regime since the last adalimumab review?	(n=157)			
Yes	NA	NA	93% (146)	
No	NA	NA	7% (11)	

CD = Crohn's disease; NA = not applicable; TNF α = tumour necrosis factor alpha.

CD: follow-up treatment at 12 months	Frequency (% , n)			
	Infliximab		Adalimumab	
	National (n=339)	YOUR SITE	National (n=181)	YOUR SITE
Follow-up treatment details continued				
If incomplete compliance, state reason (more than one may have been selected) (n=11)				
Number of missed doses	NA	NA	36% (4)	
Patient missed out some treatment weeks	NA	NA	36% (4)	
Patient stopped treatment	NA	NA	27% (3)	
Were there any adverse events since the last review?				
Yes	6% (20)		6% (11)	
What adverse events? (more than one may have been selected)				
Abdominal pain	0% (0)		0.6% (1)	
Alopecia	0.3% (1)		0% (0)	
Angioedema of upper airway	0% (0)		0.6% (1)	
Bronchospasm (cough/wheeze/dyspnoea)	0.6% (2)		0.6% (1)	
Chills	1% (4)		0.6% (1)	
Fatigue	0% (0)		0.6% (1)	
Flushing	0.3% (1)		0% (0)	
Headache	0.3% (1)		0.6% (1)	
Infection	3% (9)		1% (2)	
Itching	0.3% (1)		0% (0)	
Malignancy	0.3% (1)		0% (0)	
Rash	0.3% (1)		0.6% (1)	
Serum sickness-like reaction	0.3% (1)		0% (0)	
Other	2% (5)		2% (4)	
Is the patient currently receiving any other therapies for the management of IBD? (n=247) (n=157)				
Yes	58% (143)		59% (93)	
If yes, indicate which other therapies (more than one may have been selected)				
Allopurinol	0.4% (1)		0% (0)	
Azathioprine/mercaptopurine	45% (112)		40% (62)	
5-aminosalicylic acid	14% (34)		12% (18)	
Antibiotics	0% (0)		0.6% (1)	
Dietary therapy	0.4% (1)		0% (0)	
Methotrexate	3% (7)		7% (11)	
Mycophenolate	0% (0)		0% (0)	
Steroids	2% (6)		10% (15)	
Other	1% (3)		3% (5)	

CD = Crohn's disease; IBD = inflammatory bowel disease; NA = not applicable.

CD: follow-up treatment at 12 months	Frequency (% , n)			
	Infliximab		Adalimumab	
	National (n=339)	YOUR SITE	National (n=181)	YOUR SITE
Disease severity score				
Severity of disease	(n=193)		(n=140)	
Remission	0% (0)		0.7% (1)	
Mild	60% (116)		58% (81)	
Moderate	25% (49)		30% (42)	
Severe	15% (28)		11% (16)	

CD = Crohn's disease.

Ulcerative colitis disease details

UC: disease details	Frequency (% , n)	
	Infliximab	Adalimumab
	National (n=633)	National (n=83)
Diagnosis		
Maximal disease distribution at the time of decision to initiate biological therapy, as defined by the Montreal classification	(n=632)	
Proctitis (E1)	10% (61)	6% (5)
Left sided (E2)	45% (284)	37% (31)
Extensive (E3)	45% (287)	57% (47)
Time between date of diagnosis and date of initial treatment	(n=630)	(n=81)
<1 year ago	31% (195)	16% (13)
1–2 years ago	22% (139)	30% (24)
3–5 years ago	16% (101)	26% (21)
6–10 years ago	15% (97)	14% (11)
>10 years ago	16% (98)	15% (12)

UC = ulcerative colitis.

Ulcerative colitis initial treatment

UC: initial treatment	Frequency (% , n)	
	Infliximab	Adalimumab
	National (n=633)	National (n=83)
Consent		
Was informed consent to receive anti-TNFα treatment taken from this patient?		
Yes	99% (624)	100% (83)
No	1% (9)	0% (0)
If yes, was this verbal or written?	(n=624)	
Verbal	79% (495)	80% (66)
Written	21% (129)	21% (17)
Treatment details		
Time between date of decision to start and date of initial treatment (first loading dose)		
Median (IQR) time (days)	5 (1,17)	23 (10, 45)
What was the clinical indication for this treatment?	(n=632)	
Acute severe UC	69% (436)	40% (33)
Chronic refractory UC	28% (179)	53% (44)
Other clinical indication	1% (7)	4% (3)
Not known	2% (10)	4% (3)
Dose given at this infusion (mg/kg)	(n=485)	
5	100% (484)	NA
10	0.2% (1)	NA
Duration of infusion (mins)	(n=476)	
60	2% (7)	NA
120	96% (457)	NA
180	3% (12)	NA
Infusion completion outcome		
Completed successfully at prescribed rate	98% (622)	NA
Completed successfully at lower rate	0.8% (5)	NA
Infusion discontinued and not restarted	0.8% (5)	NA
Other	0.2% (1)	NA
Induction dose (mg)		
160/80	NA	89% (74)
80/40	NA	10% (8)
Other	NA	1% (1)
Planned maintenance dose		
40 mg every other week	NA	94% (78)
40 mg every week	NA	6% (5)

IQR = interquartile range; NA = not applicable; TNF α = tumour necrosis factor alpha; UC = ulcerative colitis.

UC: initial treatment	Frequency (% , n)	
	Infliximab	Adalimumab
	National (n=633)	National (n=83)
Treatment details continued		
Were any adverse events recorded for this treatment?		
Yes	2% (10)	1% (1)
Which acute reactions? (more than one may have been selected)		
Arthralgia	0.2% (1)	0% (0)
Bronchospasm (cough/wheeze/dyspnoea)	0.3% (2)	0% (0)
Chest pain	0.2% (1)	0% (0)
Dizziness	0.5% (3)	0% (0)
Fatigue	0.2% (1)	0% (0)
Hypotension	0.3% (2)	0% (0)
Itching	0.2% (1)	0% (0)
Nausea	0.3% (2)	0% (0)
Other	0.5% (3)	1% (1)
Is the patient receiving any concomitant therapies for the management of IBD at the time of this treatment?		
Yes	89% (561)	87% (72)
If yes, indicate which concomitant therapies (more than one may have been selected)		
Allopurinol	0.2% (1)	0% (0)
Azathioprine/mercaptopurine	46% (288)	42% (35)
5-aminosalicylic acid	46% (293)	48% (40)
Antibiotics	2% (12)	2% (2)
Dietary therapy	0.6% (4)	0% (0)
Methotrexate	4% (22)	5% (4)
Mycophenolate	0.8% (5)	0% (0)
Steroids	54% (344)	42% (35)
Tacrolimus	0.3% (2)	0% (0)
Topical	0% (0)	1% (1)
Other	2% (11)	1% (1)

IBD = inflammatory bowel disease; UC = ulcerative colitis.

UC: initial treatment	Frequency (% , n)	
	Infliximab	Adalimumab
	National (n=633)	National (n=83)
Treatment details continued		
Has the patient failed to respond or are they intolerant to immunosuppressive drugs / corticosteroids?		
Yes	64% (403)	78% (65)
If yes, indicate which previous therapies (more than one therapy may have been selected)		
Azathioprine/mercaptopurine	41% (260)	63% (52)
5-aminosalicylic acid	25% (155)	28% (23)
Antibiotics	0.6% (4)	0% (0)
Anti-TNF α	1% (7)	21% (17)
Ciclosporin	1% (7)	1% (1)
Methotrexate	5% (29)	12% (10)
Steroids	34% (218)	22% (18)
Tacrolimus	0.3% (2)	1% (1)
Other	0.3% (2)	1% (1)
Disease severity score		
Severity of disease	(n=513)	(n=71)
Mild	4% (19)	3% (2)
Moderate	24% (125)	42% (30)
Severe	72% (369)	55% (39)

TNF α = tumour necrosis factor alpha; UC = ulcerative colitis.

Ulcerative colitis follow-up treatment at 3 months

UC: follow-up treatment at 3 months	Frequency (% , n)	
	Infliximab	Adalimumab
	National (n=157)	National (n=19)
Follow-up treatment details		
Infliximab dose given at this treatment (mg/kg)		
5	99% (155)	NA
10	0.6% (1)	NA
Other	0.6% (1)	NA
Review of treatment plan		
Continue treatment	82% (128)	74% (14)
Stop treatment	19% (29)	26% (5)
If treatment was stopped, what were the reasons for stopping?	(n=29)	(n=5)
Treatment effective and discontinued	41% (12)	0% (0)
Loss of response	3% (1)	20% (1)
Poor response	17% (5)	60% (3)
Side effects / adverse events	28% (8)	20% (1)
Funding	7% (2)	0% (0)
Other	3% (1)	0% (0)
If continuing adalimumab treatment, planned continued treatment frequency		(n=14)
Every week	NA	7% (1)
Every other week	NA	93% (13)
If continuing adalimumab treatment, planned continued treatment dose (mg)		(n=14)
80	NA	7% (1)
40	NA	93% (13)
Did the patient report complete compliance with the maintenance regime since the last adalimumab review?		
Yes	NA	90% (17)
No	NA	11% (2)
If incomplete compliance, state reason		(n=2)
Patient missed out some treatment weeks	NA	50% (1)
Other compliance difference	NA	50% (1)

NA = not applicable; UC = ulcerative colitis.

UC: follow-up treatment at 3 months	Frequency (% , n)	
	Infliximab	Adalimumab
	National (n=157)	National (n=19)
Follow-up treatment details continued		
Were there any adverse events since the last review?		
Yes	9% (14)	16% (3)
What adverse events? (more than one may have been selected)		
Abdominal pain	1% (2)	0% (0)
Angioedema of upper airway	0.6% (1)	0% (0)
Blood abnormality	0.6% (1)	0% (0)
Bronchospasm (cough/wheeze/dyspnoea)	2% (3)	0% (0)
Dizziness	0% (0)	5% (1)
Fatigue	0% (0)	5% (1)
Flushing	3% (4)	5% (1)
Headache	1% (2)	0% (0)
Hypotension	1% (2)	0% (0)
Infection	3% (5)	11% (2)
Itching	0.6% (1)	0% (0)
Nausea	0.6% (1)	0% (0)
Rash	0.6% (1)	0% (0)
Suspected demyelination	0.6% (1)	0% (0)
Urticaria	0.6% (1)	0% (0)
Other	0.6% (1)	5% (1)
Is the patient currently receiving any other therapies for the management of IBD?		
Yes	74% (116)	79% (15)
If yes, indicate which other therapies (more than one may have been selected)		
Allopurinol	0.6% (1)	0% (0)
Azathioprine/mercaptopurine	55% (87)	16% (3)
Methotrexate	1% (2)	5% (1)
Steroids	7% (11)	16% (3)
5-aminosalicylic acid	32% (50)	53% (10)
Other	0.6% (1)	0% (0)
Disease severity score		
Severity of disease	(n=128)	(n=15)
Mild	56% (71)	47% (7)
Moderate	28% (36)	13% (2)
Severe	16% (21)	40% (6)

IBD = inflammatory bowel disease; UC = ulcerative colitis.

Ulcerative colitis follow-up treatment at 12 months

UC: follow-up treatment at 12 months	Frequency (% , n)	
	Infliximab	Adalimumab
	National (n=49)	National (n=3)
Follow-up treatment details		
Infliximab dose given at this treatment (mg/kg)		
5	96% (47)	NA
10	2% (1)	NA
Other	2% (1)	NA
Review of treatment plan		
Continue treatment	94% (46)	67% (2)
Stop treatment	6% (3)	33% (1)
If treatment was stopped, what were the reasons for stopping?	(n=3)	(n=1)
Treatment effective and discontinued	33% (1)	100% (1)
Side effects / adverse events	33% (1)	0% (0)
Funding	33% (1)	0% (0)
If continuing adalimumab treatment, planned continued treatment frequency		(n=2)
Every other week	NA	100% (2)
If continuing adalimumab treatment, planned continued treatment dose (mg)		(n=2)
40	NA	100% (2)
Did the patient report complete compliance with the maintenance regime since the last adalimumab review?		
Yes	NA	100% (3)
Were there any adverse events since the last review?		
Yes	2% (1)	33% (1)
What adverse events? (more than one may have been selected)		
Nausea	2% (1)	0% (0)
Other	0% (0)	33% (1)
Is the patient currently receiving any other therapies for the management of IBD?		
Yes	86% (42)	100% (3)
If yes, indicate which other therapies (more than one may have been selected)		
Azathioprine/mercaptopurine	59% (29)	67% (2)
5-aminosalicylic acid	51% (25)	33% (1)
Methotrexate	6% (3)	33% (1)
Steroids	2% (1)	33% (1)
Other	2% (1)	0% (0)

IBD = inflammatory bowel disease; NA = not applicable; UC = ulcerative colitis.

UC: follow-up treatment at 12 months	Frequency (% , n)	
	Infliximab	Adalimumab
	National (n=49)	National (n=3)
Disease severity score		
Severity of disease	(n=43)	(n=2)
Mild	51% (22)	100% (2)
Moderate	33% (14)	0% (0)
Severe	16% (7)	0% (0)

UC = ulcerative colitis.

Inflammatory bowel disease type unclassified disease details

IBDU: disease details	Frequency (% , n)	
	Infliximab	Adalimumab
	National (n=78)	National (n=24)
Diagnosis		
Maximal disease distribution at the time of decision to initiate biological therapy, as defined by the Montreal classification		
Proctitis (E1)	1% (1)	4% (1)
Left sided (E2)	44% (34)	54% (13)
Extensive (E3)	55% (43)	42% (10)
Time between date of diagnosis and date of initial treatment		
<1 year	39% (30)	13% (3)
1–2 years	28% (22)	25% (6)
3–5 years	21% (16)	25% (6)
6–10 years	5% (4)	8% (2)
>10 years	8% (6)	29% (7)

IBDU = inflammatory bowel disease type unclassified.

Inflammatory bowel disease type unclassified initial treatment

IBDU: initial treatment	Frequency (% , n)	
	Infliximab	Adalimumab
	National (n=78)	National (n=24)
Consent		
Was informed consent to receive anti-TNFα treatment taken from this patient?		
Yes	99% (77)	100% (24)
No	1% (1)	0% (0)
If yes, was this verbal or written?	(n=77)	
Verbal	71% (55)	92% (22)
Written	29% (22)	8% (2)
Treatment details		
Time between date of decision to start and date of initial treatment (first loading dose)		
Median (IQR), days	9 (2, 21)	15 (4, 30)
What was the clinical indication for this treatment?	(n=77)	
Acute severe IBDU	66% (51)	46% (11)
Chronic refractory IBDU	34% (26)	50 (12)
Other clinical indication	3% (2)	4% (1)
Dose given at this infusion (mg/kg)	(n=64)	
5	98% (63)	NA
10	2% (1)	NA
Duration of infusion (mins)	(n=63)	
120	97% (61)	NA
180	3% (2)	NA
Infusion completion outcome		
Completed successfully at prescribed rate	97% (76)	NA
Infusion discontinued and not restarted	1% (1)	NA
Other	1% (1)	NA
Induction dose (mg)		
160/80	NA	63% (15)
80/40	NA	38% (9)
Planned maintenance dose		
40 mg every other week	NA	92% (22)
40 mg every week	NA	8% (2)
Were any adverse events recorded for this treatment?		
Yes	0% (0)	0% (0)

IBDU = inflammatory bowel disease type unclassified; IQR = interquartile range; NA = not applicable; TNF α = tumour necrosis factor alpha.

IBDU: initial treatment	Frequency (% , n)	
	Infliximab	Adalimumab
	National (n=78)	National (n=24)
Treatment details continued		
Is the patient receiving any concomitant therapies for the management of IBD at the time of this treatment?		
Yes	92% (72)	88% (21)
If yes, indicate which concomitant therapies (more than one may have been selected)		
Allopurinol	0% (0)	4% (1)
Azathioprine/mercaptopurine	41% (32)	63% (15)
Methotrexate	3% (2)	8% (2)
Steroids	59% (46)	42% (10)
5-aminosalicylic acid	55% (43)	46% (11)
Antibiotics	1% (1)	0% (0)
Has the patient failed to respond or are they intolerant to immunosuppressive drugs / corticosteroids?		
Yes	65% (51)	67% (16)
If yes, indicate which previous therapies (more than one may have been selected)		
Azathioprine/mercaptopurine	41% (32)	46% (11)
Methotrexate	8% (6)	8% (2)
Steroids	27% (21)	29% (7)
Anti-TNF α	1% (1)	25% (6)
5-aminosalicylic acid	22% (17)	25% (6)
Ciclosporin	4% (3)	0% (0)
Disease severity score		
Severity of disease	(n=50)	(n=12)
Mild	8% (4)	0% (0)
Moderate	36% (18)	75% (9)
Severe	56% (28)	25% (3)

IBD = inflammatory bowel disease; IBDU = inflammatory bowel disease type unclassified; TNF α = tumour necrosis factor alpha.

Inflammatory bowel disease type unclassified follow-up treatment at 3 months

IBDU: follow-up treatment at 3 months	Frequency (% , n)	
	Infliximab	Adalimumab
	National (n=30)	National (n=12)
Follow-up treatment details		
Infliximab dose given at this treatment (mg/kg)		
5	100% (30)	NA
Review of treatment plan		
Continue treatment	93% (28)	92% (11)
Stop treatment	7% (2)	8% (1)
If treatment was stopped, what were the reasons for stopping?	(n=2)	(n=1)
Poor response	0% (0)	100% (1)
Side effects / adverse events	50% (1)	0% (0)
Other	50% (1)	0% (0)
If continuing adalimumab treatment, planned continued treatment frequency		(n=11)
Every other week	NA	100% (11)
If continuing adalimumab treatment, planned continued treatment dose (mg)		(n=11)
40	NA	100% (11)
Did the patient report complete compliance with the maintenance regime since the last adalimumab review?		
Yes	NA	100% (12)
Did the patient report any adverse events?		
Yes	3% (1)	0% (0)
Which adverse events? (more than one may have been selected)		
Bronchospasm (cough/wheeze/dyspnoea)	3% (1)	0% (0)
Dizziness	3% (1)	0% (0)
Panic attacks	3% (1)	0% (0)
Is the patient currently receiving any other therapies for the management of IBD?		
Yes	77% (23)	75% (9)
If yes, indicate which other therapies (more than one may have been selected)		
Azathioprine/mercaptopurine	57% (17)	67% (8)
Steroids	17% (5)	17% (2)
5-aminosalicylic acid	50% (15)	25% (3)

IBD = inflammatory bowel disease; IBDU = inflammatory bowel disease type unclassified; NA = not applicable.

IBDU: follow-up treatment at 3 months	Frequency (% , n)	
	Infliximab	Adalimumab
	National (n=30)	National (n=12)
Disease severity score		
Severity of disease	(n=18)	(n=5)
Mild	56% (10)	40% (2)
Moderate	33% (6)	40% (2)
Severe	11% (2)	20% (1)

IBDU = inflammatory bowel disease type unclassified.

Inflammatory bowel disease type unclassified follow-up treatment at 12 months

IBDU: follow-up treatment at 12 months	Frequency (% , n)	
	Infliximab	Adalimumab
	National (n=12)	National (n=2)
Follow-up treatment details		
Infliximab dose given at this treatment (mg/kg)		
5	100% (12)	NA
Review of treatment plan		
Continue treatment	83% (10)	50% (1)
Stop treatment	17% (2)	50% (1)
If treatment was stopped, what were the reasons for stopping?	(n=2)	(n=1)
Loss of response	50% (1)	0% (0)
Treatment effective and discontinued	50% (1)	100% (1)
If continuing adalimumab treatment, planned continued treatment frequency		(n=1)
Every week	NA	100% (1)
If continuing adalimumab treatment, planned continued treatment dose (mg)		(n=1)
40	NA	100% (1)
Did the patient report complete compliance with the maintenance regime since the last adalimumab review?		
Yes	NA	100% (2)
Did the patient report any adverse events?		
Yes	0% (0)	0% (0)
Is the patient currently receiving any other therapies for the management of IBD?		
Yes	58% (7)	100% (2)
If yes, indicate which other therapies (more than one may have been selected)		
Azathioprine/mercaptopurine	42% (5)	100% (2)
5-aminosalicylic acid	33% (4)	0% (0)
Steroids	8% (1)	50% (1)
Disease severity score		
Severity of disease	(n=10)	(n=1)
Mild	80% (8)	100% (1)
Moderate	20% (2)	0% (0)

IBD = inflammatory bowel disease; IBDU = inflammatory bowel disease type unclassified.

IBD-related surgery

Of the analysed adult patients, 1241 had one or more surgical procedures related to their IBD. The surgery performed on these patients is categorised according to whether it was carried out before or after biological therapies were started. Only surgeries for patients included in the national analysis are presented in tables 18–20. One table is given for each disease type.

Table 18 Surgical procedures in adult patients with CD

CD-related surgery	Adult patients with surgery recorded (n=1151)	
	Before starting biological therapy (n=1034)*	After starting biological therapy (n=200)*
Surgical procedure by type (% , n)		
Anterior resection	0.3% (3)	0% (0)
Appendicectomy	2% (15)	0% (0)
Cholecystectomy	1% (11)	0% (0)
Colectomy and ileostomy	6% (62)	8% (15)
Drainage of abscess	3% (30)	3% (5)
Excision of fistula	2% (15)	0% (0)
Gastric surgery	0.1% (1)	0.5% (1)
Other surgical procedure	22% (226)	25% (50)
Partial colectomy	5% (48)	2% (4)
Perianal surgery	23% (238)	24% (47)
Proctectomy	0.3% (3)	0% (0)
Right hemicolectomy / ileocaecal resection	42% (431)	16% (31)
Small bowel resection	22% (225)	22% (44)
Stoma formation	2% (21)	0.5% (1)
Stricturoplasty	4% (43)	4% (8)
Total colectomy with ileorectal anastomosis	0.4% (4)	0% (0)
Total proctocolectomy ileoanal pouch	1% (14)	0% (0)
Total proctocolectomy permanent ileostomy	3 (31)	4 (8)

*Patients may have one or more surgeries recorded.
CD = Crohn's disease.

Table 19 Surgical procedures in adult patients with UC

UC-related surgery	Adult patients with surgery recorded (n=78)	
	Before starting biological therapy (n=26)*	After starting biological therapy (n=54)*
Surgical procedure by type (% , n)		
Appendicectomy	4% (1)	0% (0)
Colectomy and ileostomy	46% (12)	74% (40)
Other surgical procedure	35% (9)	6% (3)
Partial colectomy	4% (1)	4% (2)
Perianal surgery	15% (4)	6% (3)
Right hemicolectomy / ileocaecal resection	4% (1)	0% (0)
Small bowel resection	4% (1)	0% (0)
Total proctocolectomy ileoanal pouch	15% (4)	4% (2)
Total proctocolectomy permanent ileostomy	0% (0)	9% (5)

*Patients may have one or more surgeries recorded.

UC = ulcerative colitis.

Table 20 Surgical procedures in adult patients with IBDU

IBDU-related surgery	Adult patients with surgery recorded (n=12)	
	Before starting biological therapy (n=6)*	Before starting biological therapy (n=7)*
Surgical procedure by type (% , n)		
Colectomy and ileostomy	17% (1)	71% (5)
Perianal surgery	67% (4)	14% (1)
Total proctocolectomy ileoanal pouch	17% (1)	14% (1)

*Patients may have one or more surgeries recorded.

IBDU = inflammatory bowel disease type unclassified.

Patient-reported outcome measures (PROMs)

Outcome measures have traditionally relied on disease activity indexes, but these measures fail to assess the patient's subjective view of their experience. Patient-reported outcome measures therefore evaluate quality from the patient's perspective. Typically, they are short, self-completed questionnaires that measure the patient's health status or health-related quality of life at a single point in time. The health status information is collected from patients by way of PROMs questionnaires completed before, during and after an intervention (in this case, initiation of biological therapy) and provides an indication of the outcomes or quality of care delivered to patients.

EQ-5D

The EQ-5D is a standardised instrument for use as a measure of health outcome. It provides a simple descriptive profile and a single index value for health status. It was primarily designed for self-completion by respondents and is ideally suited for use in clinics.

The EQ-5D is a descriptive system of health-related quality of life states consisting of five dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression), each of which can take one of three responses depending on level of severity – no problems / some or moderate problems / extreme problems – within a particular EQ-5D dimension. Total EQ-5D scores range from 0 (worst health / death) to 1 (best health), with an increase in score denoting improved health. Scores from each domain are weighted and converted into a single weighted summary index. The data within this report are presented in the form of a median (IQR). The EQ-5D has been shown to be valid, reliable and responsive in patients with IBD.¹⁵

In total, 1416 EQ-5D questionnaires were completed at an initial treatment for patients taking infliximab and adalimumab and for all disease types, with a median (IQR) score of 0.76 (0.66, 0.85). At 3-month follow-up, 361 EQ-5D questionnaires were completed for patients taking infliximab and adalimumab and for all disease types, with a median (IQR) score of 0.80 (0.73, 1.0). At 12-month follow-up, 57 EQ-5D questionnaires were completed for patients taking infliximab and adalimumab and for all disease types, with a median (IQR) score of 0.80 (0.69, 1.0).

The limited number of patients with EQ-5D scores at initial and follow-up treatment means that the difference between the EQ-5D scores at these timepoints could not be calculated. However, the median scores at these two stages was calculated for all patients who had a score; comparison of these medians showed an increase in the median EQ-5D score of 0.04 between initial and 3-month follow-up treatment. This may suggest a clinical improvement in quality of life after patients started biological therapies.

CUCQ-12

The CUCQ-12 is a relatively new and shortened version of the 32-item Crohn's and Colitis Questionnaire (CCQ-32) – a quality of life measurement tool developed specifically for use with patients with IBD to measure active disease and long-term monitoring of the condition.

The items in the CUCQ-12 questionnaire address the following 12 dimensions: sleeping, appetite, energy level, rushing to the toilet, being bloated, incomplete emptying of bowels, blood in stool, generally unwell, faecal incontinence, nocturnal diarrhoea, passing wind and effect on leisure activity. Each question is scored between 0 (best health) and 14 (poor health), corresponding to the number of days affected by a parameter in a fortnight, giving a total CUCQ-12 score ranging from 0 (best health) to 168 (poor health). Remission in patients with UC and CD is suggested by CUCQ-12 scores of <45 and <50, respectively. The minimum significant change in CUCQ-12 is 13 for both UC and CD. Early results have shown that the CUCQ-12 performs well in patients with IBD, with positive correlations compared with the EQ-5D and 12-item short-form (SF-12).

In total, 1256 CUCQ-12 questionnaires were completed at initial treatment for patients taking infliximab and adalimumab and for all disease types. The median (IQR) score of 68 (39, 100) suggests active IBD at this timepoint. At follow-up treatment, 332 questionnaires were completed for patients taking infliximab and adalimumab and for all disease types. The median (IQR) score was 34 (14, 60).

The limited number of patients with CUCQ-12 scores at initial and follow-up treatment means that the difference between the CUCQ-12 scores at these timepoints could not be calculated. However, the median scores at these two stages could be calculated for all patients who had a score; comparison of these medians showed a reduction in the median CUCQ-12 score of 34 between initial and follow-up treatment. This may suggest a clinically significant improvement in quality of life after starting biological therapies. The CUCQ-12 findings of the biological therapy audit will be used to inform learning and the ongoing validity assessment of this PROM tool.

Table 17 from **section 2** of this report is provided again for reference.

Table 17 PROMs questionnaire for IBD (IBD-PROM)

IBD-PROM	Initial treatment	3-month follow-up	12-month follow-up
Patients with IBD-PROM completed (% , n/N)	30% (1416/4718)	25% (384/1561)	22% (129/586)
Patients with EQ-5D data completed (% , n/N)	97% (1367/1416)	94% (361/384)	44% (57/129)
EQ-5D score, median (IQR)	0.76 (0.66, 0.85)	0.80 (0.73, 1)	0.80 (0.69, 1)
Patients with CUCQ-12 data completed (% , n/N)	89% (1256/1416)	87% (332/384)	87% (112/129)
CUCQ-12 score, median (IQR)	68 (39, 100)	34 (14, 60)	27 (10, 49)

CUCQ-12 = Crohn's and ulcerative colitis questionnaire; IBD = inflammatory bowel disease; IQR = interquartile range; PROMs = patient-reported outcome measures.

6: Participation and individual site key indicator data

Participation

Since the audit's inception, levels of participation have varied. Participation falls into one of three main categories:

- Sites that have been entering data, which are known as participating sites (or participants), which can be broken down into three further categories:
 - Those that have entered data regularly over the past year of data collection
 - Those that have previously entered data into the audit but have not done so during the past year of data collection
 - Those that have entered data but the data do not meet the audit criteria (for example, already established patients or unlocked submissions).
- Sites that have never entered any data to the audit, which are known as non-participating sites (or non-participant).
- Sites that do not administer biological therapies to their patients with IBD, which are known as not eligible.

Table 21 shows the different levels of adult site participation.

Table 21 Participation status for adult sites

Participation status for adult sites	Sites (n)
Participated with regular data entry	151
Participated but data submitted do not meet audit criteria	11
Previously participated but no data entered during past year of data collection	32
Not participated	20
Not eligible to participate	2
Total number of adult sites	216

Table 22 Adult site participation status over time

Table 22 shows participation of adult sites, trusts / health boards by country over time. Some services have reconfigured, so participating denominators vary.

Participating site	Audit reporting dates (% , n/N)			
	June 2012	August 2013	September 2014	September 2015
England				
Sites	43% (76/177)	68% (115/169)	90% (149/165)	96% (160/166)
Trusts	52% (75/143)	79% (106/135)	94% (133/141)	98% (134/137)
Northern Ireland				
Sites	17% (2/12)	67% (8/12)	92% (11/12)	92% (11/12)
Trusts	40% (2/5)	100% (5/5)	100% (5/5)	100% (5/5)
Scotland				
Sites	44% (8/18)	67% (12/18)	55% (11/20)	62% (13/21)
Health boards	80% (8/10)	82% (9/11)	64% (7/11)	91% (10/11)
Wales				
Sites	41% (7/17)	39% (7/18)	60% (9/15)	67% (10/15)
Health boards	67% (4/6)	67% (4/6)	67% (4/6)	67% (4/6)
Total				
Sites	42% (93/224)	65% (142/217)	84% (180/214)	90% (194/216)
Trusts / health boards	54% (89/164)	79% (124/157)	91% (149/163)	96% (153/159)

Key indicator data for individual sites

This table gives named key site data in alphabetical order of participating site in England, Northern Ireland, Scotland and Wales. These key indicators were agreed by the IBD programme steering group as reflecting the areas of particular importance to people with IBD. An asterisk next to the name of the site in the table denotes that the site has taken part in PANTs.

	Participation status	Crohn’s disease patients – time from diagnosis to initial treatment, years, Median (IQR)	Initial treatment Harvey Bradshaw Index, Median (IQR)	Crohn’s disease patients – remission achieved	Crohn’s disease patients – On concomitant immunosuppression at start of treatment	Crohn’s disease patients with adverse event recorded at 3 month follow-up	All patients – PROMs completed at start of treatment
Results		(n=3739) 4 (1, 12)	n=2282 8 (4, 10)	68% (502/741)	53% (1644/3080)	n=1343 8% (108)	30% (1416/4718)
England (n=167)							
Aintree University Hospitals NHS Foundation Trust							
Aintree University Hospital	Participant	n=22 3 (1, 8)	n<6	n<6	64% (14/22)	13% (1/8)	6% (2/32)
Airedale NHS Foundation Trust							
Airedale General Hospital*	Participant	n=28 2 (1, 9)	n=26 10 (7, 12)	60% (6/10)	20% (5/25)	18% (2/11)	45% (17/38)
Ashford and St Peter’s Hospitals NHS Foundation Trust							
Ashford Hospital and St Peter's Hospital	Participant but data submitted do not meet audit criteria						
Barking, Havering and Redbridge Hospitals NHS Trust							
King George Hospital and Queens Hospital combined	Participant	n=46 5 (1, 10)	n=22 11 (7, 13)	71% (5/7)	59% (27/46)	4% (1/26)	0% (0/63)
Barnsley Hospital NHS Foundation Trust							
Barnsley District General Hospital	Participant	n=50 3 (1, 12)	n<6	n=0	43% (22/51)	4% (1/24)	0% (0/68)

	Participation status	Crohn's disease patients – time from diagnosis to initial treatment, years, Median (IQR)	Initial treatment Harvey Bradshaw Index, Median (IQR)	Crohn's disease patients – remission achieved	Crohn's disease patients – On concomitant immunosuppression at start of treatment	Crohn's disease patients with adverse event recorded at 3 month follow-up	All patients – PROMs completed at start of treatment
Results		(n=3739) 4 (1, 12)	n=2282 8 (4, 10)	68% (502/741)	53% (1644/3080)	n=1343 8% (108)	30% (1416/4718)
Barts Health NHS Trust							
Newham University Hospital	Participant	n=12 2 (1, 16)	n<6	n=0	50% (6/12)	0% (0/7)	0% (0/14)
The Royal London Hospital and St Bartholomew's Hospital combined	Participant	n=28 4 (2, 10)	n=24 5 (1, 8)	90% (9/10)	73% (8/11)	0% (0/11)	56% (18/32)
Whipps Cross University Hospital	Participant but data submitted do not meet audit criteria						
Basildon and Thurrock University Hospitals NHS Foundation Trust							
Basildon Hospital*	Participant	n=24 4 (1, 15)	n=26 10 (6, 11)	67% (4/6)	57% (8/14)	0% (0/6)	52% (14/27)
Blackpool Teaching Hospitals NHS Foundation Trust							
Blackpool Victoria Hospital*	Participant	n=7 0 (0, 2)	n=8 11 (5, 13)	n<6	n<6	50% (1/2)	88% (7/8)
Bradford Teaching Hospitals Foundation Trust							
Bradford Royal Infirmary*	Participant	n=34 3 (1, 13)	n=19 5 (3, 8)	57% (4/7)	52% (12/23)	15% (2/13)	44% (18/41)
Brighton and Sussex University Hospitals NHS Trust							
Royal Sussex County Hospital* and Princess Royal Hospital combined	Participant	n=39 8 (1, 21)	n=16 6 (2, 10)	56% (5/9)	58% (22/38)	0% (0/17)	7% (4/56)
Buckinghamshire Healthcare NHS Trust							
Stoke Mandeville Hospital and Wycombe General Hospital combined	Previous participant but no data entered in past year						

	Participation status	Crohn's disease patients – time from diagnosis to initial treatment, years, Median (IQR)	Initial treatment Harvey Bradshaw Index, Median (IQR)	Crohn's disease patients – remission achieved	Crohn's disease patients – On concomitant immunosuppression at start of treatment	Crohn's disease patients with adverse event recorded at 3 month follow-up	All patients – PROMs completed at start of treatment
Results		(n=3739) 4 (1, 12)	n=2282 8 (4, 10)	68% (502/741)	53% (1644/3080)	n=1343 8% (108)	30% (1416/4718)
Burton Hospitals NHS Foundation Trust							
Queen's Hospital, Burton	Participant	n=14 3 (1, 16)	n<6	n=0	21% (3/14)	n<6	0% (0/20)
Calderdale and Huddersfield NHS Foundation Trust							
Huddersfield Royal Infirmary and Calderdale Hospital* combined	Participant	n=37 7 (1, 13)	n=7 6 (0, 12)	n<6	73% (24/33)	n<6	13% (7/54)
Cambridge University Hospitals NHS Foundation Trust							
Addenbrooke's Hospital*	Participant	n=26 11 (5, 16)	n=7 7 (5, 14)	n<6	46% (11/24)	n<6	21% (8/39)
Central Manchester University Hospitals NHS Foundation Trust							
Manchester Royal Infirmary*	Participant	n=14 2 (1, 5)	n=13 3 (2, 7)	n=0	33% (2/6)	n<6	52% (11/21)
Trafford General Hospital	Participant	n=10 2 (1, 8)	n<6	n=0	40% (4/10)	n=0	0% (0/10)
Chelsea and Westminster Hospital NHS Foundation Trust							
Chelsea and Westminster Hospital*	Participant	n<6	n<6	n<6	n<6	n<6	n<6
Chesterfield Royal Hospital NHS Foundation Trust							
Chesterfield Royal Hospital*	Participant	n=55 4 (1, 10)	n=47 8 (4, 10)	70% (14/20)	46% (24/52)	14% (3/21)	10% (7/67)
City Hospitals Sunderland NHS Foundation Trust							
Sunderland Royal Hospital*	Participant	n=11 4 (1, 10)	n=7 9 (7, 11)	n<6	n=0	n<6	100% (13/13)

	Participation status	Crohn's disease patients – time from diagnosis to initial treatment, years, Median (IQR)	Initial treatment Harvey Bradshaw Index, Median (IQR)	Crohn's disease patients – remission achieved	Crohn's disease patients – On concomitant immunosuppression at start of treatment	Crohn's disease patients with adverse event recorded at 3 month follow-up	All patients – PROMs completed at start of treatment
Results		(n=3739) 4 (1, 12)	n=2282 8 (4, 10)	68% (502/741)	53% (1644/3080)	n=1343 8% (108)	30% (1416/4718)
Colchester Hospital University NHS Foundation Trust							
Colchester General Hospital*	Participant	n=32 10 (3, 17)	n=16 14 (10, 16)	50% (3/6)	61% (17/28)	9% (2/22)	11% (4/37)
Countess of Chester Hospital NHS Foundation Trust							
Countess of Chester Hospital	Participant	n=25 6 (2, 14)	n=23 5 (1, 9)	75% (15/20)	48% (12/25)	9% (2/22)	0% (0/51)
County Durham and Darlington NHS Foundation Trust							
Darlington Memorial Hospital and Bishop Auckland Hospital combined*	Participant	n=27 3 (1, 13)	n=28 9 (6, 12)	n<6	68% (17/25)	0% (0/6)	16% (7/43)
University Hospital of North Durham	Participant	n=9 5 (2, 9)	n=9 7 (6, 10)	n<6	44% (4/9)	n<6	9% (1/11)
Croydon Health Services NHS Trust							
Croydon University Hospital	Participant	n=20 8 (1, 16)	n=16 7 (6, 10)	57% (4/7)	90% (18/20)	0% (0/7)	0% (0/23)
Dartford and Gravesham NHS Trust							
Darent Valley Hospital	Previous participant but no data entered in past year						
Derby Hospitals NHS Foundation Trust							
Royal Derby Hospital*	Participant	n=11 7 (1, 15)	n=9 9 (6, 11)	n=0	25% (2/8)	n<6	47% (8/17)
Doncaster and Bassetlaw Hospitals NHS Foundation Trust							
Doncaster Royal Infirmary* and Bassetlaw District General Hospital combined	Participant	n<6	n<6	n<6	n<6	n<6	n<6

	Participation status	Crohn's disease patients – time from diagnosis to initial treatment, years, Median (IQR)	Initial treatment Harvey Bradshaw Index, Median (IQR)	Crohn's disease patients – remission achieved	Crohn's disease patients – On concomitant immunosuppression at start of treatment	Crohn's disease patients with adverse event recorded at 3 month follow-up	All patients – PROMs completed at start of treatment
Results		(n=3739) 4 (1, 12)	n=2282 8 (4, 10)	68% (502/741)	53% (1644/3080)	n=1343 8% (108)	30% (1416/4718)
Dorset County Hospital NHS Foundation Trust							
Dorset County Hospital*	Participant	n=6 4 (1, 10)	n=6 5 (4, 11)	n<6	n=0	n<6	100% (6/6)
Ealing Hospital NHS Trust							
Ealing Hospital	Non-participant						
East and North Hertfordshire NHS Trust							
Lister Hospital* and Queen Elizabeth II Hospital combined	Participant	n=59 5 (1, 12)	n=59 9 (7, 13)	70% (14/20)	59% (30/51)	0% (0/23)	73% (52/71)
East Cheshire NHS Trust							
Macclesfield District General Hospital	Participant	n=25 5 (2, 9)	n=24 11 (9, 12)	n=0	68% (17/25)	n=0	0% (0/27)
East Kent Hospitals University NHS Foundation Trust							
William Harvey Hospital, Kent and Canterbury Hospital and Queen Elizabeth The Queen Mother Hospital combined	Participant	n=7 10 (1, 20)	n<6	n=0	43% (3/7)	n=0	0% (0/7)
East Lancashire Hospitals NHS Trust							
Royal Blackburn Hospital and Burnley District General Hospital combined	Participant	n=73 4 (1, 11)	n=48 7 (3, 11)	42% (10/24)	23% (17/75)	3% (1/40)	50% (46/93)
East Sussex Healthcare Trust							
Eastbourne District General Hospital and Conquest Hospital combined*	Participant	n=8 1 (0, 13)	n<6	n<6	n<6	n<6	40% (4/10)

	Participation status	Crohn's disease patients – time from diagnosis to initial treatment, years, Median (IQR)	Initial treatment Harvey Bradshaw Index, Median (IQR)	Crohn's disease patients – remission achieved	Crohn's disease patients – On concomitant immunosuppression at start of treatment	Crohn's disease patients with adverse event recorded at 3 month follow-up	All patients – PROMs completed at start of treatment
Results		(n=3739) 4 (1, 12)	n=2282 8 (4, 10)	68% (502/741)	53% (1644/3080)	n=1343 8% (108)	30% (1416/4718)
Epsom and St Helier University Hospitals NHS Trust							
Epsom General Hospital	Participant	n=7 3 (2, 23)	n=7 10 (9, 12)	n<6	71% (5/7)	n<6	0% (0/10)
St Helier Hospital	Participant	n=6 4 (1, 11)	n<6	n=0	83% (5/6)	n=0	17% (1/6)
Frimley Health NHS Foundation Trust							
Frimley Park Hospital*	Participant	n=32 7 (2, 16)	n=27 11 (7, 14)	70% (7/10)	78% (21/27)	13% (2/16)	14% (5/35)
Heatherwood Hospital	Non-participant						
Wexham Park Hospital	Participant	n<6	n<6	n<6	n<6	n<6	n<6
Gateshead Health NHS Foundation Trust							
Queen Elizabeth Hospital, Gateshead	Participant but data submitted do not meet audit criteria						
George Eliot Hospital NHS Trust							
George Eliot Hospital	Participant	n=37 1 (0, 2)	n<6	n=0	43% (16/37)	0% (0/12)	50% (21/42)
Gloucestershire Hospitals NHS Foundation Trust							
Gloucestershire Royal Hospital and Cheltenham General Hospital combined*	Participant	n=13 1 (0, 9)	n=17 4 (2, 8)	67% (4/6)	n=0	14% (1/7)	88% (15/17)
Great Western Hospitals NHS Foundation Trust							
Great Western Hospital	Participant	n=53 4 (1, 11)	n<6	n=0	40% (21/53)	100% (1/1)	0% (0/69)

	Participation status	Crohn's disease patients – time from diagnosis to initial treatment, years, Median (IQR)	Initial treatment Harvey Bradshaw Index, Median (IQR)	Crohn's disease patients – remission achieved	Crohn's disease patients – On concomitant immunosuppression at start of treatment	Crohn's disease patients with adverse event recorded at 3 month follow-up	All patients – PROMs completed at start of treatment
Results		(n=3739) 4 (1, 12)	n=2282 8 (4, 10)	68% (502/741)	53% (1644/3080)	n=1343 8% (108)	30% (1416/4718)
Guy's and St Thomas' NHS Foundation Trust							
Guy's Hospital and St Thomas' Hospital combined*	Participant	n=14 1 (1, 6)	n=17 5 (4, 9)	n<6	n=0	n<6	94% (16/17)
Hampshire Hospitals NHS Foundation Trust							
Basingstoke and North Hampshire Hospitals*	Participant	n=10 3 (1, 14)	n=10 9 (5, 12)	n<6	n=0	n<6	100% (10/10)
Royal Hampshire County Hospital*	Participant	n=12 2 (0, 19)	n=15 7 (4, 15)	n<6	n=0	n<6	93% (14/15)
Harrogate and District NHS Foundation Trust							
Harrogate District Hospital	Previous participant but no data entered in past year	n=8 4 (1, 7)	n<6	n=0	50% (4/8)	n=0	0% (0/10)
Heart of England NHS Foundation Trust							
Birmingham Heartlands Hospital and Solihull Hospital combined	Participant	n<6	n<6	n<6	n<6	n<6	n<6
Good Hope Hospital	Participant	n=6 5 (2, 10)	n<6	n=0	67% (4/6)	n<6	0% (0/7)
Hinchingbrooke Health Care NHS Trust							
Hinchingbrooke Hospital	Participant but data submitted do not meet audit criteria						
Homerton University Hospital NHS Foundation Trust							
Homerton University Hospital	Participant	n=49 4 (1, 12)	n=44 9 (7, 10)	32% (6/19)	84% (41/49)	5% (1/21)	6% (4/63)

	Participation status	Crohn's disease patients – time from diagnosis to initial treatment, years, Median (IQR)	Initial treatment Harvey Bradshaw Index, Median (IQR)	Crohn's disease patients – remission achieved	Crohn's disease patients – On concomitant immunosuppression at start of treatment	Crohn's disease patients with adverse event recorded at 3 month follow-up	All patients – PROMs completed at start of treatment
Results		(n=3739) 4 (1, 12)	n=2282 8 (4, 10)	68% (502/741)	53% (1644/3080)	n=1343 8% (108)	30% (1416/4718)
Hull and East Yorkshire Hospitals NHS Trust							
Hull Royal Infirmary* and Castle Hill Hospital combined	Participant	n=62 2 (0, 8)	n=49 5 (2, 7)	79% (19/24)	63% (17/27)	5% (2/40)	79% (53/67)
Imperial College Healthcare NHS Trust							
Charing Cross Hospital, Hammersmith Hospital and St Mary's Hospital combined	Previous participant but no data entered in past year						
James Paget University Hospitals NHS Foundation Trust							
James Paget Hospital*	Participant	n=6 0 (0, 3)	n=6 7 (1, 10)	n<6	n<6	n<6	83% (5/6)
Kettering General Hospital NHS Foundation Trust							
Kettering General Hospital	Previous participant but no data entered in past year						
King's College Hospital NHS Foundation Trust							
King's College Hospital	Participant	n<6	n<6	n<6	n<6	n<6	n<6
Princess Royal University Hospital	Participant	n=8 4 (1, 12)	n<6	n=0	63% (5/8)	n=0	0% (0/16)
Kingston Hospital NHS Trust							
Kingston Hospital	Participant	n=15 1 (1, 6)	n<6	n=0	73% (11/15)	n=0	0% (0/19)
Lancashire Teaching Hospitals NHS Foundation Trust							
Royal Preston Hospital and Chorley and South Ribble Hospital combined	Participant but data submitted do not meet audit criteria						

	Participation status	Crohn’s disease patients – time from diagnosis to initial treatment, years, Median (IQR)	Initial treatment Harvey Bradshaw Index, Median (IQR)	Crohn’s disease patients – remission achieved	Crohn’s disease patients – On concomitant immunosuppression at start of treatment	Crohn’s disease patients with adverse event recorded at 3 month follow-up	All patients – PROMs completed at start of treatment
Results		(n=3739) 4 (1, 12)	n=2282 8 (4, 10)	68% (502/741)	53% (1644/3080)	n=1343 8% (108)	30% (1416/4718)
Lewisham and Greenwich NHS Trust							
Lewisham Hospital	Participant	n<6	n<6	n=0	n<6	n<6	0% (0/7)
Queen Elizabeth Hospital, Woolwich	Participant but data submitted do not meet audit criteria						
London North West Healthcare NHS Trust							
Central Middlesex Hospital	Participant but data submitted do not meet audit criteria						
Northwick Park and St Mark's Hospitals Combined*	Participant	n=14 20 (8, 29)	n=16 5 (2, 10)	67% (8/12)	n=0	0% (0/12)	100% (16/16)
Luton and Dunstable Hospital NHS Foundation Trust							
Luton and Dunstable Hospital*	Participant	n<6	n<6	n=0	n=0	n<6	0% (0/6)
Maidstone and Tunbridge Wells NHS Trust							
Maidstone Hospital*	Participant	n<6	n<6	n<6	n<6	n<6	n<6
Tunbridge Wells Hospital	Participant	n=19 8 (3, 16)	n=11 9 (0, 9)	n=0	53% (10/19)	n<6	10% (2/20)
Medway NHS Foundation Trust							
Medway Maritime Hospital	Participant	n=18 4 (2, 13)	n<6	n=0	72% (13/18)	n<6	0% (0/20)
Mid Cheshire Hospitals NHS Foundation Trust							
Leighton Hospital*	Participant	n<6	n<6	n<6	n<6	n<6	n<6

	Participation status	Crohn's disease patients – time from diagnosis to initial treatment, years, Median (IQR)	Initial treatment Harvey Bradshaw Index, Median (IQR)	Crohn's disease patients – remission achieved	Crohn's disease patients – On concomitant immunosuppression at start of treatment	Crohn's disease patients with adverse event recorded at 3 month follow-up	All patients – PROMs completed at start of treatment
Results		(n=3739) 4 (1, 12)	n=2282 8 (4, 10)	68% (502/741)	53% (1644/3080)	n=1343 8% (108)	30% (1416/4718)
Mid Essex Hospitals NHS Trust							
Broomfield Hospital	Participant	n=25 6 (2, 12)	n=23 10 (9, 12)	n=0	52% (13/25)	n=0	0% (0/25)
Milton Keynes Hospital NHS Foundation Trust							
Milton Keynes Hospital*	Participant	n<6	n=8 7 (4, 11)	n<6	n=0	n<6	100% (8/8)
NHS Isle of Wight							
St Mary's Hospital	Previous participant but no data entered in past year						
Norfolk and Norwich University Hospitals NHS Foundation Trust							
Norfolk and Norwich University Hospital*	Participant	n=12 4 (2, 9)	n=12 3 (1, 6)	n<6	n=0	n<6	100% (12/12)
North Bristol NHS Trust							
Southmead hospital	Participant	n=13 3 (1, 10)	n<6	n=0	62% (8/13)	n<6	7% (1/14)
North Cumbria University Hospitals NHS Trust							
Cumberland Infirmary*	Participant	n=13 4 (2, 9)	n<6	n=0	46% (5/11)	n<6	14% (2/14)
West Cumberland Hospital*	Participant	n=9 2 (1, 8)	n<6	n=0	100% (7/7)	n<6	13% (2/15)
North Middlesex University Hospital NHS Trust							
North Middlesex University Hospital	Previous participant but no data entered in past year						

	Participation status	Crohn's disease patients – time from diagnosis to initial treatment, years, Median (IQR)	Initial treatment Harvey Bradshaw Index, Median (IQR)	Crohn's disease patients – remission achieved	Crohn's disease patients – On concomitant immunosuppression at start of treatment	Crohn's disease patients with adverse event recorded at 3 month follow-up	All patients – PROMs completed at start of treatment
Results		(n=3739) 4 (1, 12)	n=2282 8 (4, 10)	68% (502/741)	53% (1644/3080)	n=1343 8% (108)	30% (1416/4718)
North Tees and Hartlepool NHS Foundation Trust							
University Hospital of Hartlepool	Participant	n<6	n<6	n<6	n<6	n<6	n<6
University Hospital of North Tees	Participant	n=31 4 (1, 13)	n<6	n=0	55% (17/31)	11% (2/19)	13% (5/40)
Northampton General Hospital NHS Trust							
Northampton General Hospital	Participant	n=36 6 (1, 13)	n<6	n<6	44% (16/36)	0% (0/9)	0% (0/53)
Northern Devon Healthcare NHS Trust							
North Devon District Hospital	Previous participant but no data entered in past year	n<6	n<6	n<6	n<6	n<6	n<6
Northern Lincolnshire and Goole Hospitals NHS Foundation Trust							
Diana, Princess of Wales Hospital	Participant	n=26 4 (1, 9)	n<6	n=0	62% (16/26)	n<6	0% (0/45)
Scunthorpe General Hospital	Previous participant but no data entered in past year	n=9 4 (2, 10)	n<6	n=0	67% (6/9)	n<6	0% (0/10)
Northumbria Healthcare NHS Foundation Trust							
Northumbria Healthcare NHS Foundation Trust (Wansbeck, North Tyneside and Hexham General Hospitals combined)	Participant	n=28 5 (1, 12)	n=27 11 (8, 14)	43% (3/7)	61% (17/28)	0% (0/8)	38% (12/32)

	Participation status	Crohn's disease patients – time from diagnosis to initial treatment, years, Median (IQR)	Initial treatment Harvey Bradshaw Index, Median (IQR)	Crohn's disease patients – remission achieved	Crohn's disease patients – On concomitant immunosuppression at start of treatment	Crohn's disease patients with adverse event recorded at 3 month follow-up	All patients – PROMs completed at start of treatment
Results		(n=3739) 4 (1, 12)	n=2282 8 (4, 10)	68% (502/741)	53% (1644/3080)	n=1343 8% (108)	30% (1416/4718)
Nottingham University Hospital NHS Trust							
Queen's Medical Centre* and Nottingham City Hospital combined	Participant	n=7 3 (1, 17)	n=10 7 (3, 9)	n<6	n=0	33% (2/6)	100% (10/10)
Oxford University Hospitals NHS Trust							
The John Radcliffe Hospital and Horton General Hospital combined	Participant	n=36 3 (1, 8)	n<6	n=0	67% (24/36)	13% (1/8)	0% (0/41)
Peterborough and Stamford Hospitals NHS Foundation Trust							
Peterborough City Hospital	Participant	n=26 8 (2, 22)	n<6	n<6	65% (17/26)	0% (0/8)	0% (0/31)
Plymouth Hospitals NHS Trust							
Derriford Hospital*	Participant	n=9 0 (0, 7)	n=10 4 (2, 8)	n=0	n=0	0% (0/6)	93% (13/14)
Poole Hospital NHS Foundation Trust							
Poole General Hospital*	Participant	n=8 5 (0, 10)	n=8 6 (3, 8)	n=0	n=0	n<6	94% (15/16)
Portsmouth Hospitals NHS Trust							
Queen Alexandra Hospital*	Participant	n=51 6 (1, 14)	n=10 4 (4, 7)	57% (4/7)	64% (27/42)	0% (0/7)	12% (8/65)
Princess Alexandra Hospital NHS Trust							
Princess Alexandra Hospital, Harlow*	Participant	n=14 4 (0, 13)	n=17 11 (6, 15)	n<6	n=0	0% (0/6)	100% (17/17)
Royal Berkshire NHS Foundation Trust							
Royal Berkshire Hospital*	Participant	n=9 1 (1, 13)	n=10 5 (3, 14)	n<6	n=0	n<6	100% (10/10)

	Participation status	Crohn's disease patients – time from diagnosis to initial treatment, years, Median (IQR)	Initial treatment Harvey Bradshaw Index, Median (IQR)	Crohn's disease patients – remission achieved	Crohn's disease patients – On concomitant immunosuppression at start of treatment	Crohn's disease patients with adverse event recorded at 3 month follow-up	All patients – PROMs completed at start of treatment
Results		(n=3739) 4 (1, 12)	n=2282 8 (4, 10)	68% (502/741)	53% (1644/3080)	n=1343 8% (108)	30% (1416/4718)
Royal Bolton Hospital NHS Foundation Trust							
Royal Bolton Hospital	Participant	n=65 6 (2, 12)	n=45 5 (3, 9)	38% (3/8)	81% (54/67)	6% (1/16)	10% (9/91)
Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust							
Royal Bournemouth Hospital*	Participant	n=97 5 (1, 15)	n=95 7 (5, 11)	64% (28/44)	60% (55/91)	6% (3/48)	8% (10/121)
Royal Cornwall Hospitals NHS Trust							
Royal Cornwall Hospital*	Participant	n=27 7 (2, 16)	n=10 6 (2, 6)	n<6	57% (13/23)	0% (0/11)	30% (11/37)
Royal Devon and Exeter NHS Foundation Trust							
Royal Devon and Exeter Hospital*	Participant	n=47 1 (0, 4)	n=48 6 (3, 10)	81% (21/26)	n=0	4% (1/27)	86% (42/49)
Royal Free London NHS Foundation Trust							
Barnet General Hospital	Previous participant but no data entered in past year	n=6 4 (1, 15)	n=6 22 (14, 25)	n=0	83% (5/6)	n=0	0% (0/8)
Royal Free Hospital*	Participant	n=8 6 (2, 14)	n<6	n=0	50% (3/6)	n<6	42% (5/12)
Royal Liverpool and Broadgreen University Hospitals NHS Trust							
Royal Liverpool University Hospital	Participant	n=28 2 (1, 7)	n=27 7 (0, 10)	n<6	64% (18/28)	0% (0/6)	0% (0/33)
Royal Surrey County Hospital NHS Foundation Trust							
Royal Surrey County Hospital	Participant	n=7 10 (2, 27)	n=6 14 (12, 14)	n=0	71% (5/7)	n=0	0% (0/9)

	Participation status	Crohn's disease patients – time from diagnosis to initial treatment, years, Median (IQR)	Initial treatment Harvey Bradshaw Index, Median (IQR)	Crohn's disease patients – remission achieved	Crohn's disease patients – On concomitant immunosuppression at start of treatment	Crohn's disease patients with adverse event recorded at 3 month follow-up	All patients – PROMs completed at start of treatment
Results		(n=3739) 4 (1, 12)	n=2282 8 (4, 10)	68% (502/741)	53% (1644/3080)	n=1343 8% (108)	30% (1416/4718)
Royal United Hospital Bath NHS Trust							
Royal United Hospital	Non-participant						
Salford Royal NHS Foundation Trust							
Salford Royal Hospital*	Participant	n=108 7 (2, 15)	n=85 9 (8, 11)	12% (6/49)	36% (38/106)	13% (7/56)	2% (2/114)
Salisbury NHS Foundation Trust							
Salisbury District General Hospital	Participant	n=19 2 (1, 6)	n<6	n=0	37% (7/19)	n<6	0% (0/32)
Sandwell and West Birmingham Hospitals NHS Trust							
Birmingham City Hospital and Sandwell Hospital combined*	Participant	n=20 6 (1, 12)	n=11 8 (5, 9)	n<6	75% (6/8)	n<6	44% (10/23)
Sheffield Teaching Hospitals NHS Foundation Trust							
Royal Hallamshire Hospital and Northern General Hospital combined	Participant	n=145 6 (2, 13)	n=99 7 (4, 10)	64% (16/25)	44% (64/146)	0% (0/42)	65% (125/192)
Sherwood Forest Hospitals NHS Foundation Trust							
King's Mill Hospital and Newark Hospital combined*	Participant	n=30 2 (1, 9)	n=20 4 (2, 7)	67% (4/6)	33% (5/15)	10% (1/10)	55% (18/33)
South Devon Healthcare NHS Foundation Trust							
Torbay Hospital*	Participant	n=24 5 (1, 18)	n=24 8 (4, 12)	64% (7/11)	n=0	23% (3/13)	100% (24/24)

	Participation status	Crohn's disease patients – time from diagnosis to initial treatment, years, Median (IQR)	Initial treatment Harvey Bradshaw Index, Median (IQR)	Crohn's disease patients – remission achieved	Crohn's disease patients – On concomitant immunosuppression at start of treatment	Crohn's disease patients with adverse event recorded at 3 month follow-up	All patients – PROMs completed at start of treatment
Results		(n=3739) 4 (1, 12)	n=2282 8 (4, 10)	68% (502/741)	53% (1644/3080)	n=1343 8% (108)	30% (1416/4718)
South Tees Hospitals NHS Foundation Trust							
Friarage Hospital	Non-participant						
James Cook University Hospital*	Participant	n=15 2 (0, 15)	n=12 4 (2, 11)	88% (7/8)	n<6	0% (0/8)	56% (10/18)
South Tyneside NHS Foundation Trust							
South Tyneside District Hospital*	Participant	n=23 5 (2, 14)	n=24 5 (3, 7)	86% (12/14)	58% (11/19)	11% (2/18)	30% (10/33)
South Warwickshire NHS Foundation Trust							
Warwick Hospital	Participant	n=75 3 (1, 10)	n<6	n=0	32% (24/75)	n=0	0% (0/89)
Southend University Hospital NHS Foundation Trust							
Southend University Hospital	Previous participant but no data entered in past year	n<6	n<6	n=0	n<6	n<6	0% (0/11)
Southport and Ormskirk Hospital NHS Trust							
Southport District General Hospital	Previous participant but no data entered in past year						
St George's Healthcare NHS Trust							
St George's Hospital*	Participant	n=39 8 (2, 11)	n=42 10 (9, 12)	67% (10/15)	74% (26/35)	16% (3/19)	31% (15/48)

	Participation status	Crohn’s disease patients – time from diagnosis to initial treatment, years, Median (IQR)	Initial treatment Harvey Bradshaw Index, Median (IQR)	Crohn’s disease patients – remission achieved	Crohn’s disease patients – On concomitant immunosuppression at start of treatment	Crohn’s disease patients with adverse event recorded at 3 month follow-up	All patients – PROMs completed at start of treatment
Results		(n=3739) 4 (1, 12)	n=2282 8 (4, 10)	68% (502/741)	53% (1644/3080)	n=1343 8% (108)	30% (1416/4718)
St Helens and Knowsley Hospitals NHS Trust							
Whiston Hospital	Participant but data submitted do not meet audit criteria						
Stockport NHS Foundation Trust							
Stepping Hill Hospital*	Participant	n<6	n<6	n<6	n<6	n<6	n<6
Surrey and Sussex Healthcare NHS Trust							
East Surrey Hospital	Previous participant but no data entered in past year						
Tameside Hospital NHS Foundation Trust							
Tameside General Hospital*	Participant	n<6	n<6	n<6	n<6	n<6	43% (3/7)
Taunton and Somerset NHS Foundation Trust							
Musgrove Park Hospital*	Participant	n=14 4 (1, 17)	n=11 0 (0, 5)	n<6	55% (6/11)	n<6	95% (19/20)
The Dudley Group NHS Foundation Trust							
Russells Hall Hospital*	Participant	n=43 4 (1, 12)	n=39 8 (5, 10)	n<6	62% (26/42)	10% (1/10)	49% (32/65)
The Hillingdon Hospitals NHS Foundation Trust							
Hillingdon Hospital	Non-participant						
The Ipswich Hospital NHS Trust							
The Ipswich Hospital	Previous participant but no data entered in past year						

	Participation status	Crohn's disease patients – time from diagnosis to initial treatment, years, Median (IQR)	Initial treatment Harvey Bradshaw Index, Median (IQR)	Crohn's disease patients – remission achieved	Crohn's disease patients – On concomitant immunosuppression at start of treatment	Crohn's disease patients with adverse event recorded at 3 month follow-up	All patients – PROMs completed at start of treatment
Results		(n=3739) 4 (1, 12)	n=2282 8 (4, 10)	68% (502/741)	53% (1644/3080)	n=1343 8% (108)	30% (1416/4718)
The Leeds Teaching Hospitals NHS Trust							
Leeds General Infirmary*	Participant	n<6	n<6	n=0	n<6	n<6	n<6
St James's University Hospital Leeds*	Participant	n=14 5 (1, 10)	n=15 5 (2, 7)	67% (4/6)	n=0	13% (1/8)	94% (16/17)
The Mid Yorkshire Hospitals NHS Trust							
Dewsbury and District Hospital	Non-participant						
Pinderfields General Hospital and Pontefract Hospitals combined*	Participant	n=12 2 (0, 5)	n=16 2 (0, 9)	n<6	n=0	0% (0/6)	82% (14/17)
The Newcastle upon Tyne Hospitals NHS Foundation Trust							
Freeman Hospital	Participant	n=40 9 (2, 20)	n=10 11 (6, 17)	n<6	43% (17/40)	5% (1/22)	0% (0/43)
Royal Victoria Infirmary, Newcastle*	Participant	n=23 3 (1, 10)	n=24 6 (3, 10)	83% (15/18)	n=0	5% (1/19)	100% (24/24)
The Pennine Acute Hospitals NHS Trust							
The Royal Oldham Hospital, Fairfield General Hospital, North Manchester General Hospital and Rochdale Infirmary combined*	Participant	n=88 5 (1, 11)	n=11 5 (4, 10)	n<6	55% (43/78)	n<6	9% (10/107)
The Queen Elizabeth Hospital King's Lynn NHS Foundation Trust							
The Queen Elizabeth Hospital	Previous participant but no data entered in past year						

	Participation status	Crohn's disease patients – time from diagnosis to initial treatment, years, Median (IQR)	Initial treatment Harvey Bradshaw Index, Median (IQR)	Crohn's disease patients – remission achieved	Crohn's disease patients – On concomitant immunosuppression at start of treatment	Crohn's disease patients with adverse event recorded at 3 month follow-up	All patients – PROMs completed at start of treatment
Results		(n=3739) 4 (1, 12)	n=2282 8 (4, 10)	68% (502/741)	53% (1644/3080)	n=1343 8% (108)	30% (1416/4718)
The Rotherham NHS Foundation Trust							
Rotherham Hospital	Participant	n=13 5 (2, 12)	n=6 11 (5, 18)	n<6	54% (7/13)	n<6	0% (0/17)
The Royal Wolverhampton Hospitals NHS Trust							
Cannock Chase Hospital	Participant	n<6	n<6	n=0	n<6	n<6	n<6
New Cross Hospital*	Participant	n=60 5 (2, 12)	n=46 8 (5, 9)	47% (9/19)	46% (25/54)	0% (0/21)	26% (22/84)
The Shrewsbury and Telford Hospital NHS Trust							
Royal Shrewsbury Hospital* and Princess Royal Hospital combined	Participant	n=13 6 (1, 11)	n=15 5 (4, 10)	71% (5/7)	n<6	0% (0/8)	88% (14/16)
United Lincolnshire Hospitals NHS Trust							
Grantham and District Hospital*	Participant	n=6 1 (1, 6)	n=6 8 (1, 8)	n<6	n<6	n<6	14% (1/7)
Lincoln County Hospital*	Participant	n=18 2 (1, 5)	n=6 6 (5, 10)	n<6	53% (8/15)	n<6	13% (3/23)
Pilgrim Hospital	Participant	n=17 5 (1, 17)	n<6	n=0	53% (9/17)	17% (1/6)	0% (0/19)
University College London Hospitals NHS Foundation Trust							
University College Hospital*	Participant	n=70 4 (1, 8)	n=57 7 (3, 9)	73% (16/22)	75% (51/68)	10% (3/30)	4% (3/80)

	Participation status	Crohn's disease patients – time from diagnosis to initial treatment, years, Median (IQR)	Initial treatment Harvey Bradshaw Index, Median (IQR)	Crohn's disease patients – remission achieved	Crohn's disease patients – On concomitant immunosuppression at start of treatment	Crohn's disease patients with adverse event recorded at 3 month follow-up	All patients – PROMs completed at start of treatment
Results		(n=3739) 4 (1, 12)	n=2282 8 (4, 10)	68% (502/741)	53% (1644/3080)	n=1343 8% (108)	30% (1416/4718)
University Hospitals of North Midlands NHS Trust							
County Hospital	Participant but data submitted do not meet audit criteria						
The Royal Stoke University Hospital*	Participant	n<6	n<6	n<6	n<6	n<6	n<6
University Hospital of South Manchester NHS Foundation Trust							
Wythenshawe Hospital*	Participant	n=30 4 (1, 10)	n=29 10 (6, 14)	83% (5/6)	59% (10/17)	0% (0/6)	34% (13/38)
University Hospital Southampton NHS Foundation Trust							
Southampton General Hospital*	Participant	n=48 3 (1, 10)	n=47 7 (4, 13)	52% (11/21)	46% (5/11)	10% (3/30)	77% (46/60)
University Hospitals Birmingham NHS Foundation Trust							
Queen Elizabeth Hospital, Birmingham	Participant	n=134 8 (3, 15)	n=14 8 (3, 11)	n=0	44% (60/135)	11% (11/102)	5% (9/170)
New Queen Elizabeth Hospital Birmingham*	Participant	n=7 3 (0, 15)	n=9 4 (0, 10)	n<6	n=0	n<6	100% (10/10)
University Hospitals Coventry and Warwickshire NHS Trust							
University Hospital, Coventry*	Participant	n=18 4 (1, 19)	n=18 5 (3, 9)	n<6	n=0	n<6	100% (18/18)
University Hospitals of Bristol NHS Foundation Trust							
Bristol Royal Infirmary*	Participant	n=10 3 (1, 5)	n=6 6 (2, 9)	n<6	44% (4/9)	n<6	15% (2/13)

	Participation status	Crohn's disease patients – time from diagnosis to initial treatment, years, Median (IQR)	Initial treatment Harvey Bradshaw Index, Median (IQR)	Crohn's disease patients – remission achieved	Crohn's disease patients – On concomitant immunosuppression at start of treatment	Crohn's disease patients with adverse event recorded at 3 month follow-up	All patients – PROMs completed at start of treatment
Results		(n=3739) 4 (1, 12)	n=2282 8 (4, 10)	68% (502/741)	53% (1644/3080)	n=1343 8% (108)	30% (1416/4718)
University Hospitals of Leicester NHS Trust							
Leicester Royal Infirmary	Previous participant but no data entered in past year	n=8 2 (1, 3)	n<6	n=0	38% (3/8)	n=0	0% (0/8)
Leicester General Hospital*	Participant	n<6	n<6	n<6	n<6	n<6	n<6
University Hospitals of Morecombe Bay NHS Foundation Trust							
Furness General and Royal Lancaster Infirmary and Westmorland General Hospitals combined	Participant	n=22 9 (2, 20)	n<6	n=0	59% (13/22)	n<6	0% (0/27)
Walsall Healthcare NHS Trust							
Walsall Manor Hospital	Previous participant but no data entered in past year	n=21 2 (1, 8)	n=19 13 (10, 16)	n<6	52% (11/21)	n<6	65% (20/31)
Warrington and Halton Hospitals NHS Foundation Trust							
Warrington District General Hospital*	Participant	n=18 5 (2, 11)	n=17 7 (5, 13)	n<6	n<6	n<6	57% (13/23)
West Hertfordshire Hospitals NHS Trust							
Watford General Hospital* and Hemel Hempstead General Hospital combined	Participant	n=66 3 (1, 10)	n=48 10 (8, 13)	65% (11/17)	51% (32/63)	5% (2/40)	4% (3/70)
West Middlesex University Hospital NHS Trust							
West Middlesex University Hospital*	Participant	n=17 5 (2, 13)	n=17 10 (8, 12)	n=0	56% (9/16)	n<6	5% (1/22)

	Participation status	Crohn's disease patients – time from diagnosis to initial treatment, years, Median (IQR)	Initial treatment Harvey Bradshaw Index, Median (IQR)	Crohn's disease patients – remission achieved	Crohn's disease patients – On concomitant immunosuppression at start of treatment	Crohn's disease patients with adverse event recorded at 3 month follow-up	All patients – PROMs completed at start of treatment
Results		(n=3739) 4 (1, 12)	n=2282 8 (4, 10)	68% (502/741)	53% (1644/3080)	n=1343 8% (108)	30% (1416/4718)
West Suffolk Hospitals NHS Foundation Trust							
West Suffolk Hospital	Participant	n=15 4 (1, 12)	n=14 14 (11, 21)	29% (2/7)	27% (4/15)	10% (1/10)	0% (0/17)
Western Sussex Hospitals NHS Trust							
St Richard's Hospital	Participant	n=19 6 (1, 15)	n=11 8 (2, 9)	n=0	68% (13/19)	n=0	0% (0/25)
Worthing Hospital*	Participant	n=7 0 (0, 8)	n<6	n<6	n<6	n<6	57% (4/7)
Weston Area Health Trust							
Weston General Hospital*	Participant	n=19 11 (1, 20)	n=20 9 (5, 12)	n<6	21% (3/14)	11% (1/9)	69% (18/26)
Whittington Health NHS Trust							
Whittington Hospital	Participant but data submitted do not meet audit criteria						
Wirral University Teaching Hospital NHS Foundation Trust							
Arrowe Park Hospital	Participant	n=31 5 (2, 19)	n=16 7 (6, 9)	n<6	36% (11/31)	0% (0/7)	0% (0/31)
Worcestershire Acute Hospitals NHS Trust							
Alexandra Hospital	Not eligible						
Worcestershire Royal Hospital	Previous participant but no data entered in past year	n=12 10 (2, 16)	n<6	n=0	67% (8/12)	n=0	0% (0/17)

	Participation status	Crohn's disease patients – time from diagnosis to initial treatment, years, Median (IQR)	Initial treatment Harvey Bradshaw Index, Median (IQR)	Crohn's disease patients – remission achieved	Crohn's disease patients – On concomitant immunosuppression at start of treatment	Crohn's disease patients with adverse event recorded at 3 month follow-up	All patients – PROMs completed at start of treatment
Results		(n=3739) 4 (1, 12)	n=2282 8 (4, 10)	68% (502/741)	53% (1644/3080)	n=1343 8% (108)	30% (1416/4718)
Wrightington, Wigan and Leigh NHS Foundation Trust							
Royal Albert Edward Infirmary*	Participant	n=7 6 (2, 33)	n=7 7 (1, 11)	n<6	n=0	n<6	100% (7/7)
Wye Valley NHS Trust							
County Hospital, Hereford	Participant	n=19 2 (1, 9)	n=18 9 (7, 14)	38% (3/8)	42% (8/19)	0% (0/8)	0% (0/20)
Yeovil District Hospital NHS Foundation Trust							
Yeovil District Hospital*	Participant	n=37 6 (1, 16)	n=23 6 (4, 7)	60% (6/10)	36% (11/31)	33% (7/21)	92% (54/59)
York Teaching Hospital NHS Foundation Trust							
Scarborough General Hospital	Previous participant but no data entered in past year						
York Hospital	Participant	n=15 4 (1, 12)	n<6	n=0	60% (9/15)	n=0	0% (0/18)
Northern Ireland (n=12)							
Belfast Health and Social Care Trust							
Belfast City Hospital	Participant	n=30 3 (1, 10)	n=7 6 (5, 8)	n=0	67% (20/30)	n<6	23% (8/35)
Mater Hospital	Previous participant but no data entered in past year						
Royal Victoria Hospital	Participant	n=15 5 (0, 14)	n<6	n=0	80% (12/15)	n=0	0% (0/16)

	Participation status	Crohn's disease patients – time from diagnosis to initial treatment, years, Median (IQR)	Initial treatment Harvey Bradshaw Index, Median (IQR)	Crohn's disease patients – remission achieved	Crohn's disease patients – On concomitant immunosuppression at start of treatment	Crohn's disease patients with adverse event recorded at 3 month follow-up	All patients – PROMs completed at start of treatment
Results		(n=3739) 4 (1, 12)	n=2282 8 (4, 10)	68% (502/741)	53% (1644/3080)	n=1343 8% (108)	30% (1416/4718)
Northern Health and Social Care Trust							
Antrim Area Hospital	Previous participant but no data entered in past year						
Causeway Hospital	Participant	n=8 5 (1, 8)	n<6	n=0	25% (2/8)	n=0	0% (0/13)
South Eastern Health and Social Care Trust							
Downe Hospital	Non-participant						
Lagan Valley Hospital	Participant	n=6 3 (1, 5)	n=6 11 (7, 16)	n=0	50% (3/6)	n<6	0% (0/6)
Ulster Hospital	Participant	n<6	n<6	n<6	n<6	n<6	n<6
Southern Health and Social Care Trust							
Craigavon Area Hospital	Previous participant but no data entered in past year	n=8 7 (1, 14)	n<6	n=0	88% (7/8)	n=0	9% (1/11)
Daisy Hill Hospital	Participant	n=7 3 (0, 10)	n<6	n=0	43% (3/7)	n<6	44% (4/9)
Western Health and Social Care Trust							
Altnagelvin Area Hospital	Previous participant but no data entered in past year	n=8 13 (3, 22)	n=8 10 (4, 13)	n=0	50% (4/8)	n=0	0% (0/9)
South West Acute Hospital	Previous participant but no data entered in past year						

	Participation status	Crohn’s disease patients – time from diagnosis to initial treatment, years, Median (IQR)	Initial treatment Harvey Bradshaw Index, Median (IQR)	Crohn’s disease patients – remission achieved	Crohn’s disease patients – On concomitant immunosuppression at start of treatment	Crohn’s disease patients with adverse event recorded at 3 month follow-up	All patients – PROMs completed at start of treatment
Results		(n=3739) 4 (1, 12)	n=2282 8 (4, 10)	68% (502/741)	53% (1644/3080)	n=1343 8% (108)	30% (1416/4718)
Scotland (n=21)							
NHS Ayrshire and Arran							
University Hospital Ayr	Non-participant						
University Hospital Crosshouse	Previous participant but no data entered in past year						
NHS Borders							
Borders General Hospital	Previous participant but no data entered in past year						
NHS Dumfries and Galloway							
Dumfries and Galloway Royal Infirmary	Participant	n<6	n<6	n<6	n<6	n<6	n<6
NHS Fife							
Queen Margaret Hospital	Non-participant						
Victoria Hospital*	Participant	n<6	n<6	n<6	n<6	n<6	n<6
NHS Forth Valley							
Forth Valley Royal Hospital*	Participant	n=46 4 (1, 9)	n=18 4 (0, 8)	86% (6/7)	65% (22/34)	5% (1/22)	96% (65/68)
NHS Grampian							
Aberdeen Royal Infirmary	Non-participant						

	Participation status	Crohn’s disease patients – time from diagnosis to initial treatment, years, Median (IQR)	Initial treatment Harvey Bradshaw Index, Median (IQR)	Crohn’s disease patients – remission achieved	Crohn’s disease patients – On concomitant immunosuppression at start of treatment	Crohn’s disease patients with adverse event recorded at 3 month follow-up	All patients – PROMs completed at start of treatment
Results		(n=3739) 4 (1, 12)	n=2282 8 (4, 10)	68% (502/741)	53% (1644/3080)	n=1343 8% (108)	30% (1416/4718)
NHS Greater Glasgow and Clyde							
Glasgow Royal Infirmary*	Participant	n=11 5 (1, 7)	n=11 5 (3, 9)	n<6	n=0	n<6	91% (10/11)
Inverclyde Royal Hospital	Previous participant but no data entered in past year						
Royal Alexandra Hospital	Previous participant but no data entered in past year						
Southern General Hospital	Non-participant						
Victoria Infirmary	Non-participant						
Western Infirmary	Non-participant						
NHS Highland							
Raigmore Hospital	Non-participant						
NHS Lanarkshire							
Hairmyres Hospital	Participant	n=9 8 (2, 14)	n=8 8 (4, 9)	n<6	44% (4/9)	n<6	0% (0/9)
Monklands Hospital	Participant	n=14 8 (1, 17)	n=7 9 (5, 10)	n<6	57% (8/14)	n<6	43% (6/14)
Wishaw General Hospital	Previous participant but no data entered past year						

	Participation status	Crohn’s disease patients – time from diagnosis to initial treatment, years, Median (IQR)	Initial treatment Harvey Bradshaw Index, Median (IQR)	Crohn’s disease patients – remission achieved	Crohn’s disease patients – On concomitant immunosuppression at start of treatment	Crohn’s disease patients with adverse event recorded at 3 month follow-up	All patients – PROMs completed at start of treatment
Results		(n=3739) 4 (1, 12)	n=2282 8 (4, 10)	68% (502/741)	53% (1644/3080)	n=1343 8% (108)	30% (1416/4718)
NHS Lothian							
St John’s Hospital at Howden	Non-participant						
Western General Hospital and Royal Infirmary of Edinburgh combined*	Participant	n=17 4 (1, 9)	n=14 7 (4, 10)	n<6	n<6	0% (0/6)	62% (13/21)
NHS Tayside							
Ninewells Hospital*	Participant	n=15 5 (2, 18)	n=7 6 (0, 8)	n=0	47% (7/15)	n<6	23% (6/26)
Wales (n=16)							
Abertawe Bro Morgannwg University Health Board							
Morriston Hospital	Not eligible						
Princess of Wales Hospital	Non-participant						
Aneurin Bevan University Health Board							
Nevill Hall Hospital	Participant	n=41 4 (1, 8)	n=24 6 (2, 10)	n<6	49% (20/41)	0% (0/9)	46% (23/50)
Royal Gwent Hospital	Participant	n=18 4 (1, 11)	n=16 8 (4, 10)	n<6	44% (8/18)	n<6	75% (18/24)

	Participation status	Crohn’s disease patients – time from diagnosis to initial treatment, years, Median (IQR)	Initial treatment Harvey Bradshaw Index, Median (IQR)	Crohn’s disease patients – remission achieved	Crohn’s disease patients – On concomitant immunosuppression at start of treatment	Crohn’s disease patients with adverse event recorded at 3 month follow-up	All patients – PROMs completed at start of treatment
Results		(n=3739) 4 (1, 12)	n=2282 8 (4, 10)	68% (502/741)	53% (1644/3080)	n=1343 8% (108)	30% (1416/4718)
Betsi Cadwaladr University Health Board							
Glan Clwyd Hospital	Non-participant						
Llandudno General Hospital	Previous participant but no data entered in past year						
Wrexham Maelor Hospital	Participant	n=38 3 (1, 13)	n=19 10 (8, 12)	n<6	45% (17/38)	7% (2/29)	19% (8/42)
Ysbyty Gwynedd	Participant but data submitted do not meet audit criteria						
Cardiff and Vale University Health Board							
University Hospital Llandough	Participant	n=10 8 (3, 16)	n=10 6 (3, 8)	n=0	64% (7/11)	n=0	39% (5/13)
University Hospital of Wales	Previous participant but no data entered in past year	n=25 3 (1, 12)	n=22 5 (3, 9)	89% (8/9)	76% (19/25)	0% (0/9)	78% (21/27)
Cwm Taf University Health Board							
Prince Charles Hospital	Non-participant						
Royal Glamorgan Hospital	Non-participant						

	Participation status	Crohn's disease patients – time from diagnosis to initial treatment, years, Median (IQR)	Initial treatment Harvey Bradshaw Index, Median (IQR)	Crohn's disease patients – remission achieved	Crohn's disease patients – On concomitant immunosuppression at start of treatment	Crohn's disease patients with adverse event recorded at 3 month follow-up	All patients – PROMs completed at start of treatment
Results		(n=3739) 4 (1, 12)	n=2282 8 (4, 10)	68% (502/741)	53% (1644/3080)	n=1343 8% (108)	30% (1416/4718)
Hywel Dda University Health Board							
Bronglais General Hospital	Participant	n<6	n<6	n<6	n<6	n<6	n<6
Glangwili General Hospital	Previous participant but no data entered in past year						
Prince Philip Hospital	Non-participant						
Withybush General Hospital	Participant	n=17 5 (1, 13)	n=16 8 (6, 10)	n<6	77% (13/17)	n<6	30% (6/20)

CD = Crohn's disease; IQR = interquartile range; PROMs = patient-reported outcome measures.

Appendices

Appendix 1: Acronyms used in this report

Anti-TNF α	Anti-tumour necrosis factor alpha
AoMRC	Academy of Medical Royal Colleges
CD	Crohn's disease
CEEU	Clinical Effectiveness and Evaluation Unit
CUCQ-12	Crohn's and ulcerative colitis questionnaire
HBI	Harvey–Bradshaw index
HQIP	Healthcare Quality Improvement Partnership
IBD	Inflammatory bowel disease
IBDU	Inflammatory bowel disease type unclassified
IQR	Interquartile range
NCAPOP	National Clinical Audit and Patient Outcomes Programme
NICE	National Institute for Health and Care Excellence
PANTs	Personalised Anti-TNF Therapy in Crohn's disease study
PCDAI	Paediatric Crohn's Disease Activity Index
PROMs	Patient-reported outcome measures
RCN	Royal College of Nursing
RCP	Royal College of Physicians
SCCAI	Simple Clinical Colitis Activity Index
UC	Ulcerative colitis

Appendix 2: Biological therapy audit governance

Audit governance

The fourth round of the UK IBD audit is guided by the multidisciplinary IBD programme steering group, which is a collaborative partnership between gastroenterologists (the British Society of Gastroenterology), colorectal surgeons (the Association of Coloproctology of Great Britain and Ireland), patients (Crohn's and Colitis UK), physicians (the RCP), nurses (the Royal College of Nursing (RCN)), pharmacists (the Royal Pharmaceutical Society), dietitians (the British Dietetic Association) and paediatric gastroenterologists (the British Society of Paediatric Gastroenterology, Hepatology and Nutrition).

The audit is commissioned by HQIP as part of the National Clinical Audit and Patient Outcomes Programme (NCAPOP). The audit is managed by the Clinical Effectiveness and Evaluation Unit of the RCP. Each hospital identified an overall clinical lead who was responsible for data collection and entry for their IBD service. Data were collected by hospitals using a standardised method.

Any enquiries in relation to the work of the UK IBD audit can be directed to ibd.audit@rcplondon.ac.uk.

IBD programme steering group members

The names of members of the biological therapy audit subgroup are shown in bold. This is the group of people tasked with leading this particular element of the UK IBD audit and who contributed considerably to the development of this element of work.

Association of Coloproctology of Great Britain and Ireland

Mr Omar Faiz, consultant colorectal surgeon, St Mark's Hospital, Harrow

Mr Graeme Wilson, consultant colorectal surgeon, Western General Hospital, Edinburgh

British Dietetic Association

Ms Katie Keetarut, senior IBD dietitian, University College Hospital, London

British Society of Gastroenterology

Dr Ian Arnott, clinical director of the IBD programme, chair of the UK IBD audit steering group; consultant gastroenterologist, Western General Hospital, Edinburgh

Dr Stuart Bloom, consultant gastroenterologist, University College Hospital, London

Dr Keith Bodger, consultant physician and gastroenterologist, University Hospital Aintree, Liverpool

Dr Fraser Cummings, consultant gastroenterologist, University Hospital Southampton

Professor Chris Probert, consultant gastroenterologist, Royal Liverpool University Hospital

Dr Ian Shaw, IBD programme associate director; consultant gastroenterologist, Gloucestershire Royal Hospital

Dr Graham Turner, consultant gastroenterologist, Royal Victoria Hospital, Belfast

Professor John Williams, consultant gastroenterologist, Abertawe Bro Morgannwg University Health Board; director, Health Informatics Unit, RCP

British Society of Paediatric Gastroenterology, Hepatology and Nutrition

Dr Charles Charlton, consultant paediatric gastroenterologist, Queens Medical Centre, Nottingham

Dr Sally Mitton, consultant paediatric gastroenterologist, St George's Hospital, London

Dr Richard Russell, consultant paediatric gastroenterologist, Royal Hospital for Sick Children (Yorkhill), Glasgow

Crohn's and Colitis UK (NACC)

Mr David Barker, chief executive

Mr Peter Canham, patient involvement adviser

Ms Jackie Glatter, health service development adviser

Revd Ian Johnston, patient representative

Primary Care Society for Gastroenterology

Dr Jamie Dalrymple, GP partner, Drayton and St Faiths medical practice

Royal College of Nursing

Ms Kay Crook, paediatric gastroenterology clinical nurse specialist, St Mark's Hospital, Harrow

Ms Diane Hall, clinical nurse specialist, Heartlands Hospital, Birmingham

Dr Karen Kemp, IBD clinical nurse specialist, Manchester Royal Infirmary

Royal College of Physicians

Ms Rhona Buckingham, operations director, CEEU

Ms Kajal Mortier, project manager, UK IBD programme

Ms Susan Murray, programme manager, UK IBD programme

Ms Aimee Protheroe, programme development manager, UK IBD disease programme

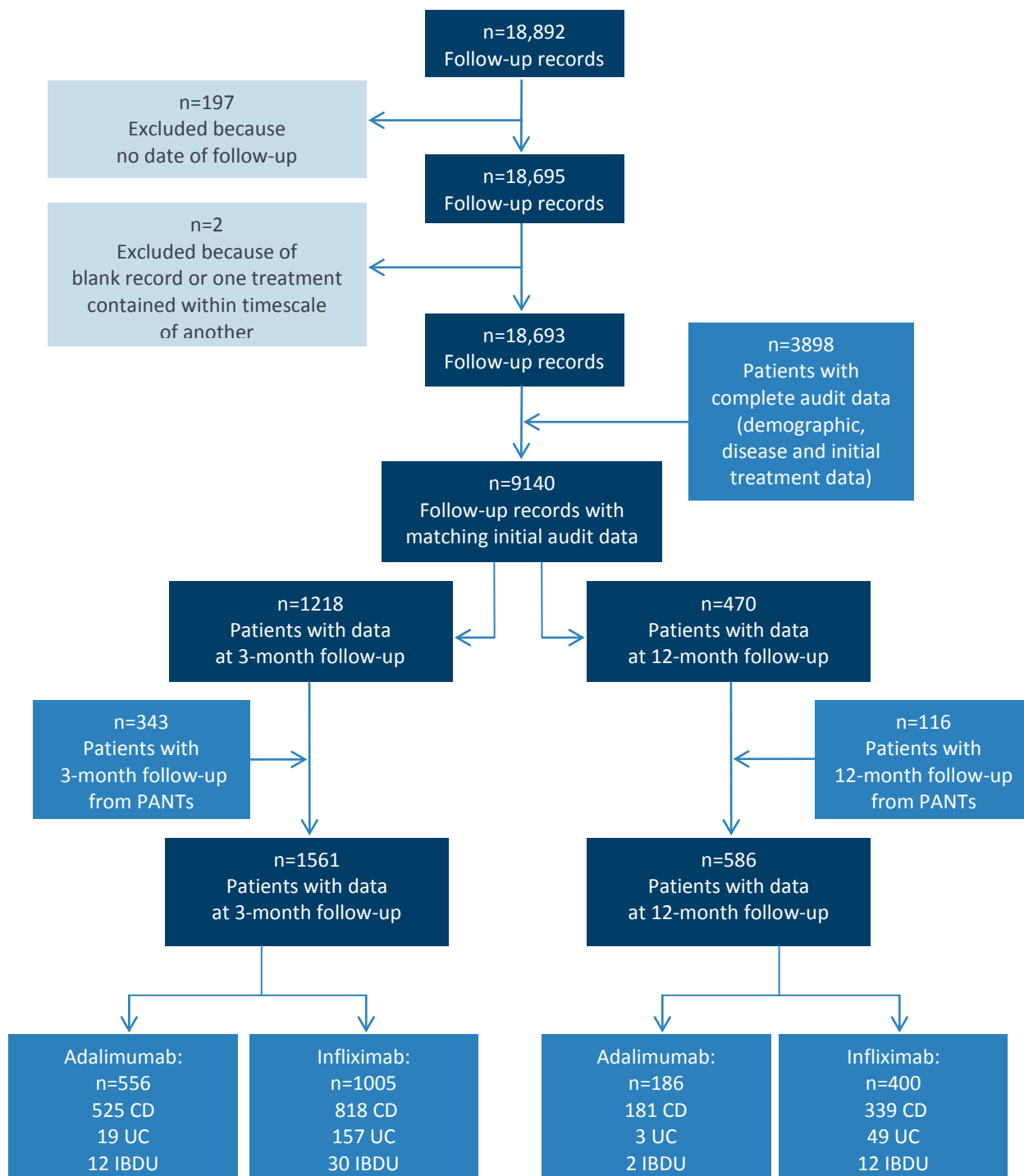
Dr Kevin Stewart, clinical director, CEEU

Royal Pharmaceutical Society of Great Britain

Ms Anja St Clair-Jones, lead pharmacist – surgery and digestive diseases, Royal Sussex County Hospital, Brighton

Appendix 3: Consort diagram – follow-up treatment

Fig 3 Consort diagram for follow-up treatment of adult patients. CD = Crohn's disease; IBDU = inflammatory bowel disease type unclassified; PANTs = Personalised Anti-TNF Therapy in Crohn's disease study; UC = ulcerative colitis.



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